

Policy Matters #3

# **Understanding Medical Abortion**

## Policy, Politics, and Women's Health

S. Marie Harvey, Christy A. Sherman,  
Sheryl Thorburn Bird, and Jocelyn Warren

Research Program on Women's Health  
Center for the Study of Women in Society  
University of Oregon

## **About the Series: Policy Matters**

This series considers issues of public policy affecting women and their families and communities. While our emphasis is on Oregon and the Pacific Northwest, the issues we address often affect women across regions, national borders, and racial, ethnic, and class lines. The goal of the series is to gather, analyze, and interpret information that will be valuable to the public, researchers, and those involved in the development of policies designed to create a brighter future for our communities.

This report was published by the Center for the Study of Women in Society, University of Oregon. Copyright 2002.

Authors: S. Marie Harvey, Christy A. Sherman,  
Sheryl Thorburn Bird, and Jocelyn Warren

Designer and Graphic Artist: Christine Beneda

Price: \$10.00

## **About the Center for the Study of Women in Society**

The Center for the Study of Women in Society (CSWS) is a multi-disciplinary research center founded at the University of Oregon in 1973. CSWS generates, supports, and disseminates research on gender and all aspects of women's lives. Currently, CSWS supports three major research initiatives: Women in the Northwest; the Feminist Humanities Project; and the Research Program on Women's Health. In addition, CSWS provides highly competitive research grants to UO faculty members and graduate students.

Center for the Study of Women in Society  
1201 University of Oregon  
Eugene, Oregon 97403-1201  
(541) 346-5015  
[csws@oregon.uoregon.edu](mailto:csws@oregon.uoregon.edu)  
<http://csws.uoregon.edu/>



# **Understanding Medical Abortion**

Policy, Politics, and Women's Health

**Policy Matters Paper #3**

S. Marie Harvey, Christy A. Sherman,  
Sheryl Thorburn Bird, and Jocelyn Warren

Research Program on Women's Health  
Center for the Study of Women in Society  
University of Oregon

November 2002

## **Series: Policy Matters**

A Publication of the Center for the Study of Women in Society  
University of Oregon, Eugene, Oregon

### **Policy Matters Paper #3**

Understanding Medical Abortion  
Policy, Politics, and Women's Health

By S. Marie Harvey, Christy A. Sherman, Sheryl Thorburn Bird,  
and Jocelyn Warren

© Copyright 2002 by the University of Oregon. Eugene, Oregon.

All rights reserved. Printed in the United States.

Center for the Study of Women in Society  
1201 University of Oregon  
Eugene, Oregon 97403-1201  
(541) 346-5015  
[csws@oregon.uoregon.edu](mailto:csws@oregon.uoregon.edu)  
<http://csws.uoregon.edu/>

# Contents

<b>Advisors</b> .....	<b>VIII</b>
<b>Acknowledgments</b> .....	<b>IX</b>
<b>Preface</b> .....	<b>1</b>
<b>Introduction</b> .....	<b>3</b>
<b>Section 1 – What is Medical Abortion?</b> .....	<b>5</b>
The 3 M’s: Mifepristone, Methotrexate, and Misoprostol	
What Do We Know About Mifepristone (RU 486)?	
What Do We Know About Methotrexate?	
<b>Section 2 – Why Medical Abortion and Why Now?</b> .....	<b>15</b>
Access to Abortion	
Options in Abortion Methods	
<b>Section 3 – Access to Medical Abortion in the United States:</b>	
<b>What Are the Political and Legal Barriers?</b> .....	<b>23</b>
What Is the Role of Politics in Medical Abortion Legislation and Policy?	
What Are the Political Strategies Used to Limit Medical Abortion?	
What Are the Laws and Policies That May Restrict Access to Medical Abortion?	
What Are the Challenges Ahead?	
<b>Section 4 – Access to Medical Abortion in the United States:</b>	
<b>What Are the Barriers for Medical Abortion Providers?</b> .....	<b>31</b>
Additional Staff Training and Time Needed to Counsel Women Regarding Medical Abortion	
Multiple Office Visits for Administration of Medical Abortion	
Ultrasound Examination	
Access to Surgical Back-up for Incomplete Medical Abortion	
Malpractice Insurance Issues	
Third Party Reimbursement	
Additional Obstacles for New Abortion Providers	
<b>Section 5 – Moving Forward</b> .....	<b>35</b>
Recommendations	
Ensuring Access to Medical Abortion	
<b>References</b> .....	<b>39</b>
<b>Glossary</b> .....	<b>45</b>
<b>Resources</b> .....	<b>49</b>

## Advisors

We gratefully acknowledge the generous contributions of our advisors (listed below), without whom this project would not have been possible. While they deserve much of the credit for what is right with *Understanding Medical Abortion*, they cannot be held responsible for mistakes, omissions, and other errors. Likewise, all opinions expressed are those of the authors.

**Katrina Abuabara, M.A.**

The Population Council, Inc.  
México City, México

**Linda J. Beckman, Ph.D.**

Alliant International University  
Los Angeles, California

**Jennifer Blasdell, J.D.**

National Abortion Federation  
Washington, D.C.

**Debra Bufton, M.P.H.**

Abortion Access Project  
Portland, Oregon

**Henry P. David, Ph.D.**

Transnational Family Research Institute  
Bethesda, Maryland

**Charlotte Ellertson, Ph.D.**

Ibis Reproductive Health  
Boston, Massachusetts

**Ann Gerhardt, M.P.H.**

National Abortion Federation  
Washington, D.C.

**Stanley Henshaw, Ph.D.**

New York, New York

**Jeffrey T. Jensen, M.D., M.P.H.**

Oregon Health and Science University  
Portland, Oregon

**Carole Joffe, Ph.D.**

The University of California, Davis  
Davis, California

**Michael Klitsch**

EngenderHealth  
New York, New York

**Kitty Piercy**

Planned Parenthood Health Services of  
Southwestern Oregon  
Eugene, Oregon

**Laureen Tews, M.P.H.**

National Abortion Federation  
Washington, D.C.



## **Acknowledgements**

In addition to our advisors, the authors wish to thank the following people for their contributions to *Understanding Medical Abortion*—Meredith Roberts Branch, Diana Taylor, Cheri Brooks, Beth Hege Piatote, Jan Emerson, and Sunshine McBride.

## About the Authors

S. Marie Harvey, DrPH, MPH, is the Director of the Research Program on Women's Health at the Center for the Study of Women in Society and Associate Professor of Public Health at the University of Oregon.

Christy A. Sherman, PhD, is a Research Scientist at the Oregon Research Institute in Eugene, Oregon.

Sheryl Thorburn Bird, PhD, MPH, is Associate Professor in the Department of Public Health at Oregon State University in Corvallis, Oregon.

Jocelyn Warren, MPH, is a Research Assistant in the Research Program on Women's Health at the Center for the Study of Women in Society, University of Oregon, and a graduate student in the Department of Public Health, Oregon State University, Corvallis, Oregon.

# Preface

Since the *Roe v Wade* decision legalizing abortion in 1973, perhaps no goal had been more eagerly anticipated by the abortion rights movement in the United States than the availability of mifepristone, commonly known as “RU-486,” or the “French abortion pill.” Approved for use in France in 1988—with the French Minister of Health’s famous assertion that the pill was the “moral property” of French women,<sup>1</sup>—the campaign to bring the drug to the U.S. took another twelve years, given the inevitable entanglement in domestic antiabortion politics. Now, two years since the FDA’s final approval in September 2000, clearly the fondest hopes of the prochoice movement for this drug—that it would dramatically increase the number of new abortion providers, and spread access to historically underserved areas—have not yet occurred. (Nor for that matter, have the dire predictions of the antiabortion movement come to pass: that this drug was dangerous, would be dispensed by untrained physicians, and would result in numerous injuries and deaths from uncontrolled bleeding).

Rather what has transpired since September 2000 is a widespread educational effort about medical abortion within various sectors of the medical community. Groups such as the National Abortion Federation (NAF) and Planned Parenthood Federation of America, whose clinics provide the majority of abortions performed in the United States, have intensified their ongoing efforts to

introduce their membership to regimens governing mifepristone use, as well as another form of medical abortion involving the drug methotrexate, a cancer drug that has for some time been used for the “off-label” purpose of pregnancy termination. Additionally, NAF and other prochoice medical groups such as Physicians for Reproductive Choice and Health, the American Women’s Medical Association and the Association of Reproductive Health professionals have formed a consortium—the Medical Abortion Education Project—whose purpose is to bring awareness of these new regimens to medical circles beyond the quite small world of existing abortion providers.

But these intensive educational efforts within the medical community have not yet been matched by similar efforts oriented toward the general public or policy makers. Many Americans still remain confused between the “abortion pill” (mifepristone) and “the morning after pill” (emergency contraception). The latter, if used within 72 hours of unprotected intercourse, can prevent a pregnancy from occurring; it cannot terminate a pregnancy already established. Many legislators and policymakers, moreover—even those who are supporters of abortion rights—are not aware of the various regulatory and bureaucratic barriers that must be overcome to achieve the previously mentioned goals of raising the numbers of “new” abortion providers, that is those who

are not currently providers of surgical abortion, and bringing abortion provision to some of those 85% of U.S. counties currently without such services.<sup>2</sup>

*Understanding Medical Abortion* is thus a particularly welcome addition to the literature on medical abortion. In impressively clear and straightforward terms, the authors review the history of FDA approval of mifepristone in the U.S., explain the medical regimens involved in both mifepristone and methotrexate abortions, debunk the misinformation spread by antiabortion forces about the safety of these regimens, offer an overview of the current status of abortion provision in this country, and demonstrate the promise of medical abortion to improve an unacceptably low level of access for many American women. Most importantly, however, this monograph outlines the numerous challenges that exist for those health care providers who wish to begin to offer this service, and offers a number of excellent recommendations to overcome these obstacles.

Reading *Understanding Medical Abortion* makes clear that these new regimens, like surgical abortion, are, medically speaking, relatively simple procedures with a very high degree of efficacy and safety. But politically speaking, there is no area of medicine in the United States that is more scrutinized and more regulated than abortion services. As a colleague and I have recently written, the struggle to integrate mifepristone into mainstream medical circles in the U.S. is one of attempting to “normalize the exceptional.”<sup>3</sup> To put this issue in perspective, however, we can learn much from an important recent report on the experience of mifepristone in Europe.<sup>4</sup> Reporting on France, Great Britain, and Sweden, the authors note that in those countries—in a political environment far less divided about abortion than our own—it took a full decade

for mifepristone provision to take hold within medical establishments. Most importantly, though, in the European context mifepristone has started to live up to one of its major public health promises—since the introduction of this drug, a higher proportion of all abortions in each country are now taking place earlier in pregnancy. In spite of the unique challenges abortion services face in the United States, we can be optimistic that in the long run, medical abortion will have a similar impact here—and the intelligent analysis and wise recommendations offered by *Understanding Medical Abortion* will surely contribute to this effort.

Carole Joffe, Ph.D.  
Professor of Sociology,  
University of California, Davis,  
and Adjunct Professor of Obstetrics  
and Gynecology,  
University of California, San Francisco.

# Introduction

Early medical abortion has the potential to expand women's access to abortion services in the U.S. and provide women with a choice of abortion methods. Mifepristone and methotrexate, the two drugs most often used in medical abortion, are safe and effective in terminating early pregnancies. However, despite the attention given to the approval of mifepristone (also known as RU-486 and Mifeprex™) by the U.S. Food and Drug Administration in 2000, many misconceptions and gaps in understanding about medical abortion persist.

This monograph synthesizes what is currently known about medical abortion and provides an overview of the legal and political issues that have shaped its practice in the U.S. In order to address some of the needs of new providers, organizations such as the National Abortion Federation offer training and other resources related to the practice of medical abortion. However, people outside the medical community, especially legislators, policymakers, and the media, also can have a significant impact on the accessibility and acceptability of medical abortion. This monograph is intended for this latter group, with the intention of increasing understanding of medical abortion and providing information and discussion useful in creating policy that supports the provision of medical abortion. *Understanding Medical Abortion: Policy, Politics, and Women's Health* is shaped by the authors' public

health background and belief that full reproductive choice, including the freedom to choose abortion for termination of an unintended pregnancy, is essential to the health and well-being of women.

The monograph is divided into five chapters. The first chapter defines medical abortion and provides information about mifepristone and methotrexate. It includes the medical regimens associated with both drugs. The second chapter examines obstacles to surgical abortion provision in the U.S. and the potential of medical abortion to expand access and increase options for women who choose abortion. The third chapter addresses the political and legal challenges to medical abortion provision in the U.S., including restrictive laws that may extend to medical abortion. The fourth chapter addresses the challenges that providers who offer medical abortion may face. Based on the information and discussion in the previous chapters, the recommendations made in the final chapter are aimed at removing obstacles to medical abortion, improving women's knowledge of medical abortion regimens, and promoting the diffusion of medical abortion practice in the U.S.

If current trends continue, 43% of women in the United States will have had an abortion by age 45.<sup>5</sup> Although abortion services have become highly politicized in the U.S., the public health benefits of safe, legal abortion

are clear. Since abortion was legalized, the declines in abortion-related and pregnancy-related deaths and disability among U.S. women have been dramatic.<sup>6</sup> We believe that medical abortion, like abortion in general, should be included in the full range of reproductive health care services offered to women. Besides giving women a choice of methods, medical abortion may also allow women to make pregnancy decisions earlier than was the case previously.

We hope this monograph will contribute to the understanding of medical abortion among policymakers, legislators and the media. Although this monograph focuses on specific health care delivery and public policy changes, these changes must be addressed within the larger context of women in society. The reproductive health needs of women are inextricably linked to gender inequality, sexism, and racism, and the increasing feminization of poverty. Thus, long term solutions to improving the health and well-being of women, men, and families will require not only the implementation of changes such as those outlined in this monograph, but also the active involvement of public health professionals, women's health advocates, and health care providers in political and social change. Bringing medical abortion into the mainstream of American medicine could improve abortion practice in the U.S. and enhance women's health.

# What is Medical Abortion?

Medical abortion is the termination of early pregnancy using a drug or combination of drugs that are administered orally, intramuscularly, and/or vaginally, first causing the pregnancy to terminate and then causing the uterus to expel the products of conception. In contrast to medical abortion, surgical abortion involves inserting instruments through the cervix into the uterus and removing the products of conception. Below we describe the two methods of medical abortion available in the United States today.

## The 3 M's: Mifepristone, Methotrexate and Misoprostol

There are three medications used in the U.S. for medical abortion: mifepristone (also known as RU-486 or “the French abortion pill”), methotrexate, and misoprostol. *Mifepristone* (brand name Mifeprex™) is an anti-progesterone that alters the uterine lining and disrupts attachment of a fertilized egg. Mifepristone has been approved by the U.S. Food and Drug Administration (FDA) for medical abortion. *Methotrexate* (brand name Folex®), an anti-metabolite, stops cell division in the developing placenta thereby interfering with cell growth and further attachment to the uterine lining.<sup>7, 8</sup> Methotrexate was approved by the FDA in

1953 and has been used in the treatment of cancer, severe psoriasis, severe arthritis, and ectopic pregnancy. Both mifepristone and methotrexate are most often used in conjunction with a third medication, misoprostol. *Misoprostol* (brand name Cytotec®) is a prostaglandin analogue which softens the cervix and stimulates uterine contractions to expel the products of conception. Misoprostol has been approved by the FDA for the treatment of ulcers and is commonly used in labor induction to thin, relax, soften and open the cervix.<sup>9, 10</sup>

## Off-Label Use and Methotrexate

The use of methotrexate in medical abortion is an off-label use. *Off-label* refers to the use of a drug for a disease or condition other than the indication for which it was approved by the FDA. This does *not* mean that off-label use is inherently risky, experimental, or novel. Off-label use of drugs is an integral feature of medical practice and often reflects approaches that have been extensively reported in medical literature. The American Medical Association (AMA) estimates that off-label uses account for 40% to 60% of the prescriptions written each year.\*

*\*Beck JM, Azari ED. FDA, off-label use, and informed consent: Debunking myths and misconceptions. Food Drug Law J. 1998;53(1):71-104.*

# What Do We Know About Mifepristone (RU 486)?

## History of Mifepristone and its Journey to the U.S.

Mifepristone was developed in 1981 by the French pharmaceutical firm, Roussel-Uclaf. Drug manufacturers in the U.S., however, were reluctant to be involved in the production and distribution of mifepristone because anti-choice groups threatened consumer boycotts.<sup>11</sup> Therefore, despite overwhelming evi-

---

\*The terms *effectiveness* and *efficacy* are both used in presenting findings from studies on medical abortion. *Efficacy* usually refers to a drug's ability to produce the intended result in a clinical trial. *Effectiveness* usually refers to a drug's ability to produce the intended result in a real world setting. Within this document, we use *effectiveness* in reference to both clinical and real world settings.

---

dence of the safety and effectiveness<sup>12</sup> of mifepristone for the termination of early pregnancy, the FDA did not approve mifepristone until September, 2000. The following time line provides an overview

of key events in the journey from initial product development to FDA approval.<sup>12-15</sup>

## What is Mifepristone and How Does it Work?

Mifepristone is a synthetic steroid that blocks the action of progesterone, which is necessary to maintain pregnancy. Blocking the action of progesterone is believed to produce changes in the endometrium (uterine lining), inducing menstrual bleeding and the shedding of the uterine lining. In addition, the drop in progesterone causes the cervix to soften and uterine contractions to begin.<sup>16</sup> Misoprostol is then administered to further stimulate contractions, expelling the products of conception.

## How is Mifepristone Administered?

The FDA specified a regimen at the time it issued its approval of mifepristone.

However, other evidence-based regimens are commonly used.

- **FDA Regimen.** The FDA-approved regimen requires three office visits – one for administration of mifepristone, one for administration of the prostaglandin (misoprostol), and a final visit two weeks after administration of mifepristone to confirm completion of the abortion. The regimen provides for medical abortion as early as when a pregnancy can be confirmed, and was approved for use through seven weeks, or 49 days, since the last menstrual period (LMP).<sup>17</sup>

### Step 1: Mifepristone administration –

The patient takes a single oral dose of 600 mg of mifepristone.

### Step 2: Misoprostol administration –

Two days after taking the mifepristone, the patient returns to the provider. If a complete abortion has not yet occurred, the patient takes a single oral dose of 400 mcg of misoprostol.

### Step 3: Post-treatment examination –

Approximately two weeks after administration of mifepristone the patient returns for a clinical or ultrasound exam to confirm that a complete abortion has occurred.

- **Evidence-based Regimens.** Research is continuing on new regimens for medical abortion. Many providers are using regimens other than the FDA-specified regimen for medical abortion with equal or greater effectiveness. For example, some providers allow home administration of misoprostol. These regimens differ in mode of administration of the misoprostol, timing of administration, dose of medications, and gestational age at which mifepristone can be given.



**Mode of administration.** Many studies have demonstrated that vaginal administration of misoprostol (as opposed to oral) results in comparable or higher rates of complete abortion, sustained effectiveness at higher gestational ages, lower incidence of gastrointestinal side effects, and more rapid completion of the abortion.<sup>18-21</sup>

**Dose of medications.** Although the FDA regimen specifies 600 mg of mifepristone and 400 mcg of misoprostol, studies have shown comparable rates of effectiveness with a lower dose of mifepristone (200 mg) and a higher dose of misoprostol (e.g., 800 mcg).<sup>21-24</sup>

**Gestational age of pregnancy.** Studies have shown mifepristone-induced abortions can be successfully performed up to 56 days LMP with oral administration of misoprostol, compared with the shorter time frame specified by the FDA (up to 49 days LMP).<sup>23</sup> Abortions can also be successfully performed up to 63 days LMP with vaginal administration of misoprostol.<sup>23, 25</sup>

**Timing of administration.** Studies have documented that misoprostol can be administered anywhere from 24 hours to 72 hours after administration of mifepristone up through a gestational age of 63 days or less.<sup>26, 27</sup>

## How Long Does it Take?

A few women using the FDA-approved mifepristone/misoprostol regimen will experience expulsion of the pregnancy prior to the administration of misoprostol. More than half will experience a complete abortion within four hours of administration of misoprostol, and 70% to 80% within 24 hours.<sup>22, 23, 26-29</sup> Ninety-five to 97% of women

will have a complete abortion within two weeks. However, for some women a complete abortion may take three to four weeks.<sup>22, 23, 26, 27, 29, 30</sup> There are several treatment options for women with an incomplete abortion, including continued observation, repeat administration of misoprostol, and surgical completion. Several factors, including the woman's symptoms and her preferences, will determine the course of treatment for incomplete abortion.

## Is Mifepristone Safe?

- **Mifepristone Has Been Used Safely by Millions of Women Worldwide.** Mifepristone has been used safely by millions of women globally,<sup>31-35</sup> including thousands of women in the U.S.<sup>22, 23, 26, 27, 29</sup> The most common side effects are bleeding and cramping. Many women also experience nausea, vomiting, or diarrhea.<sup>36</sup>
- **Serious Side Effects Are Rare.** Serious complications following a mifepristone/

## Countries Where Mifepristone has been Approved for Use as an Abortifacient

Austria	the Netherlands
Belgium	Norway
China	Russia
Denmark	South Africa
Finland	Spain
France	Sweden
Germany	Switzerland
Great Britain	Tunisia
Greece	Ukraine
Israel	United States
Luxembourg	

Source: Jones RK, Henshaw SK. Mifepristone for early medical abortion: Experiences in France, Great Britain, and Sweden. *Perspect Sex Reprod Health.* 2002;34(3):154.

misoprostol-induced abortion are extremely rare; infection and surgical intervention for serious medical complications have occurred in fewer than 1% of women.<sup>21, 22, 26, 29, 36</sup> A commonly reported outcome of medical abortion is heavy bleeding. However less than 1% of women undergoing a mifepristone/misoprostol-induced abortion have required blood transfusions<sup>22, 24, 27, 29</sup> or surgical intervention<sup>23, 27, 37</sup> due to heavy bleeding. Less than 0.2% of women have required transfusions in three large clinical trials.<sup>29, 35, 38</sup>

A small number of cases of serious adverse events have been reported,<sup>39, 40</sup> including ruptured ectopic pregnancy, bacterial infection, and one case of myocardial infarction. Two patient deaths have occurred, one resulting from systemic bacterial infection and one following hemorrhage due to a ruptured ectopic pregnancy; however, no causal relationships have been established between these events and the use of mifepristone/misoprostol.<sup>39</sup>

## Is Mifepristone Effective?

Mifepristone with misoprostol is very effective for termination of early pregnancy. For pregnancies of seven weeks or less, effectiveness rates exceed 95%.<sup>22, 23</sup> Effectiveness can be slightly lower in pregnancies of longer duration depending upon the regimen used, but across many regimens the effectiveness averages 85% or greater up to nine weeks LMP.<sup>21</sup> In the trial conducted in the U.S. by the Population Council, effectiveness reached 77% at 57-64 days LMP (approximately eight to nine weeks LMP). Studies using vaginal administration of misoprostol have achieved effectiveness rates up to 98% and 99%.<sup>21, 23</sup>

## Who May Provide Medical Abortions Using Mifepristone?

Under FDA regulations, mifepristone (Mifeprex™) is distributed only to licensed physicians who submit a signed *Prescriber's Agreement* to the pharmaceutical distributor, Danco Laboratories. The *Prescriber's Agreement* stipulates that mifepristone will be provided by or under the supervision of a physician who can accurately assess the duration of pregnancy, diagnose ectopic pregnancy, and provide surgical abortion in cases of incomplete abortion or make arrangements for referral to a provider of surgical abortion. Some state laws allow non-physician providers (e.g., certified physician assistants, nurse practitioners) who work under the supervision of a physician to dispense mifepristone.<sup>17</sup> Providers must also have women who are seeking a medical abortion sign a *Patient Agreement* form that describes the regimen, give them a *Medication Guide*, and notify the distributor of mifepristone of any adverse events.

## What Do We Know About Methotrexate?

### History of Methotrexate

Methotrexate has been available in the U. S. since 1953 when it was approved by the FDA for the treatment of cancer. Since 1982, methotrexate also has been used to treat ectopic pregnancy. Providers and researchers began to investigate and use methotrexate for medical abortion in the 1990s when they became frustrated with the delays in bringing mifepristone to the U.S.<sup>41, 42</sup> This drug is not approved by the FDA for early pregnancy termination, but because it is available by prescription, physicians may legally pre-

## Prescriber's Agreement

### MIFEPREX™ (Mifepristone) Tablets, 200 mg

We are pleased that you wish to become a provider of Mifeprex\* (Mifepristone) Tablets, 200 mg, which is indicated for the medical termination of intrauterine pregnancy through 49 days from the first day of the patient's last menstrual period (see full prescribing information). Prescribing Information, Mifeprex Medication Guide and PATIENT AGREEMENT forms will be provided together with your order of Mifeprex.

Prior to establishing your account and receiving your first order, you must sign and return this letter to the distributor, indicating that you have met the qualifications outlined below and will observe the guidelines outlined below. If you oversee more than one office facility, you will need to list each facility on your order form prior to shipping the first order.

By signing the reverse side, you acknowledge receipt of the PRESCRIBER'S AGREEMENT and agree that you meet these qualifications and that you will follow these guidelines for use. You also understand that if you do not follow these guidelines, the distributor may discontinue distribution of the drug to you.

Under Federal law, Mifeprex must be provided by or under the supervision of a physician who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the prescribing information of Mifeprex. The prescribing information is attached to this letter, and is also

available by calling our toll free number, 1-877-4 Early Option (1-877-432-7596), or logging on to our website, [www.earlyoptionpill.com](http://www.earlyoptionpill.com).

In addition to these qualifications, you must provide Mifeprex in a manner consistent with the following guidelines.

- Under Federal law, each patient must be provided with a Medication Guide. You must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and PATIENT AGREEMENT, give her an opportunity to read and discuss them, obtain her signature on the PATIENT AGREEMENT, and sign it yourself.
- The patient's follow-up visit at approximately 14 days is very important to confirm that a complete termination of pregnancy has occurred and that there have been no complications. You must notify Danco Laboratories in writing as discussed in the Package Insert under the heading DOSAGE AND ADMINISTRATION in the event of an on-going pregnancy which is not terminated subsequent to the conclusion of the treatment procedure.
- While serious adverse events associated with the use of Mifeprex are rare, you must report any hospitalization, transfusion or other serious event to Danco Laboratories, identifying the patient solely by package serial number to ensure patient confidentiality.
- Each package of Mifeprex has a serial number. As part of maintaining complete records for each patient, you must record this serial number in each patient's record.

Danco Laboratories, LLC  
P.O. Box 4816  
New York, NY 10185  
1-877-4 Early Option (1-877-432-7596)  
[www.earlyoptionpill.com](http://www.earlyoptionpill.com)

# Patient Agreement

## MIFEPREX™ (Mifepristone) Tablets, 200 mg

1. I have read the attached Medication Guide for using Mifeprex and misoprostol to end my pregnancy.
2. I discussed the information with my health care provider (provider).
3. My provider answered all my questions and told me about the risks and benefits of using Mifeprex and misoprostol to end my pregnancy.
4. I believe I am no more than 49 days (7 weeks) pregnant.
5. I understand that I will take Mifeprex in my provider's office.
6. I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3).
7. My provider gave me advice on what to do if I develop heavy bleeding or need emergency care due to the treatment.
8. Bleeding and cramping do not mean that my pregnancy has ended. Therefore, I must return to my provider's office in about 2 weeks (about Day 14) after I take Mifeprex to be sure that my pregnancy has ended and that I am well.
9. I know that, in some cases, the treatment will not work. This happens in about 5 to 8 women out of 100 who use this treatment.
10. I understand that if my pregnancy continues after any part of the treatment, there is a chance that there may be birth defects. If my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about my choices, which may include a surgical procedure to end my pregnancy.
11. I understand that if the medicines I take do not end my pregnancy and I decide to have a surgical procedure to end my pregnancy, or if I need a surgical procedure to stop bleeding,

my provider will do the procedure or refer me to another provider who will. I have the provider's name, address and phone number.

12. I have my provider's name, address and phone number and know that I can call if I have any questions or concerns.
13. I have decided to take Mifeprex and misoprostol to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.
14. I will do the following:
  - return to my provider's office in 2 days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant.
  - return to my provider's office about 14 days after beginning treatment to be sure that my pregnancy has ended and that I am well

Patient Signature: \_\_\_\_\_

Patient Name (print): \_\_\_\_\_

Date: \_\_\_\_\_

The patient signed the PATIENT AGREEMENT in my presence after I counseled her and answered all her questions. I have given her the Medication Guide for mifepristone.

Provider's Signature: \_\_\_\_\_

Name of Provider print: \_\_\_\_\_

Date: \_\_\_\_\_

After the patient and the provider sign this PATIENT AGREEMENT, give 1 copy to the patient before she leaves the office and put 1 copy in her medical record. Give a copy of the Medication Guide to the patient.

scribe it for this use. Evidence supports its safety and effectiveness for this purpose. Besides being widely available, methotrexate is relatively inexpensive, especially in the injectable form.

## What Is Methotrexate and How Does It Work?

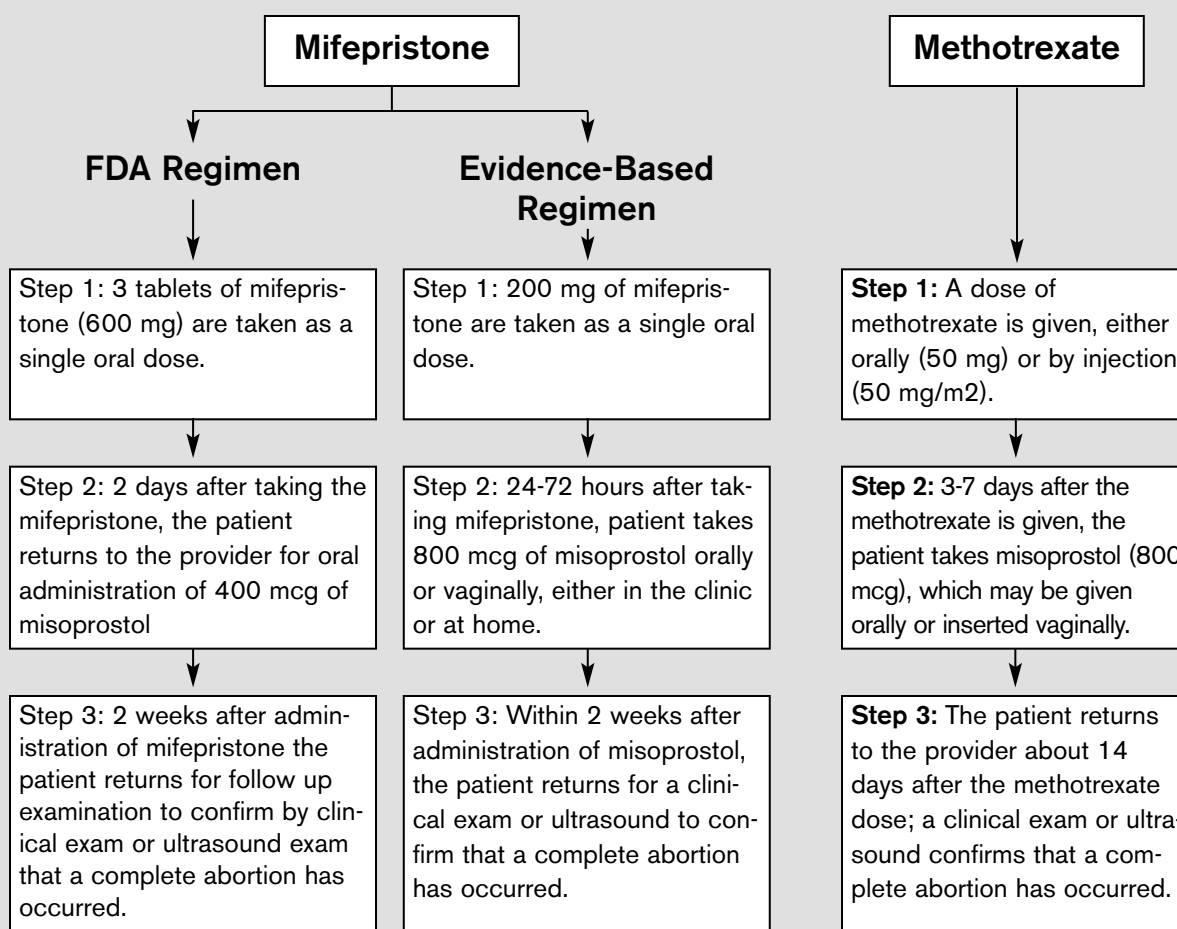
Methotrexate is an anti-metabolite that inhibits DNA synthesis and interferes with

cell growth.<sup>7, 41, 43</sup> As such, methotrexate stops the process of fetal development.<sup>41</sup>

## How Is Methotrexate Administered?

Methotrexate can be given by injection or taken orally. As with mifepristone, methotrexate is followed by the administration of misoprostol, which can be administered either orally or vaginally but is most commonly administered vaginally.<sup>21</sup>

## Flow Chart



Sources: Kahn JG, Becker BJ, Maclsaal L, et al. The effectiveness of medical abortion: A meta-analysis. *Contraception*. 2000;61:29-40; Stewart FH, Wells ES, Flinn SK, Weitz TA. *Early Medical Abortion: Issues for Practice*. San Francisco, CA: University of California, San Francisco, Center for Reproductive Health Research and Policy; 2000; US Food and Drug Administration. Mifepristone questions and answers. Available at: <http://fda.gov/cder/drug/infopage/mifepristone/mifepristone-qa.htm>. Accessed January 15, 2001.

Methotrexate regimens vary in dosage, in administration (i.e., methotrexate taken orally or by injection), and in the number of days between methotrexate and misoprostol administration.

**Step 1: Methotrexate administration –**

The patient is either given 50 mg/m<sup>2</sup> of methotrexate by injection or takes 50 mg orally.

**Step 2: Misoprostol administration –**

Three to seven days after taking the methotrexate, the patient returns to the provider. If a complete abortion has not occurred, the patient is given 800 mcg of misoprostol, administered orally or vaginally.

**Step 3: Post-treatment examination**

–Approximately two weeks after administration of methotrexate the patient returns for a clinical or ultrasound exam to confirm that a complete abortion has occurred. This visit can occur earlier.

**How Long Does it Take?**

Few women expel the products of conception prior to the administration of the misoprostol. Fifty to 70% of women experience a complete abortion within 24 hours of the administration of misoprostol, with some differences in rates resulting from mode of administration of methotrexate.<sup>21,44</sup> The percentage increases in the 24 hours following a second dose of misoprostol, with the cumulative rate of complete abortion increasing to 75% of women.<sup>7,44</sup> By the end of two weeks up to 83% of women experience a complete abortion,<sup>44,45</sup> and, after 21 days, rates of completed abortion exceed 90%.<sup>7,44</sup> Women who are found to have an incomplete abortion at the post-treatment examination may opt for surgical abortion or may continue to wait.<sup>46</sup> Some women are willing to wait weeks for the bleeding to stop, while others are not. Surgical abortion is strongly recommended for those women who have an ongoing

**Comparison Chart for Mifepristone and Methotrexate**

	<i>Mifepristone/Misoprostol</i>	<i>Methotrexate/Misoprostol</i>
What is it?	Blocks the progesterone hormone needed to maintain pregnancy.	Stops process of implantation.
How is it used?	Both drugs are given orally, two days apart, in the FDA-approved regimen.	Methotrexate is injected or taken orally; misoprostol is taken orally or vaginally 3-7 days later.
Effectiveness	92%-96%	85%-96%
Common side effects	Bleeding and cramping	Bleeding and cramping
Availability in the U.S.	FDA approved for early abortion.	FDA approved for other uses. Evidence-based use for early abortion

Data source: Henry J. Kaiser Family Foundation. Fact Sheet: Abortion in the U.S. Available at: [http://www.kff.org/content/archive/1432/ru/486\\_ls.html](http://www.kff.org/content/archive/1432/ru/486_ls.html). Accessed September 12, 2002.

ing pregnancy at the second week follow-up visit.<sup>7, 41, 47</sup>

## Is Methotrexate Safe?

- **Methotrexate Has Been Used Safely in the U. S. for Years.** Methotrexate has been used safely since the 1950s for cancer treatment and since the early 1980s for ectopic pregnancy. There are substantial data regarding the safety and effectiveness of methotrexate for medical abortion.<sup>48-56</sup> When used at dosages indicated for medical abortion, common side effects of methotrexate include bleeding, cramping, and gastrointestinal problems such as nausea, vomiting, and diarrhea.
- **Serious Side Effects Are Rare.** When methotrexate is used for medical abortion, serious side effects occur in less than 1% of patients.<sup>21, 41</sup> Like mifepristone/misoprostol induced abortion, bleeding is a commonly reported side effect. However, fewer than 1% of women have required intervention for heavy bleeding.<sup>50, 52, 53</sup>

## Is Methotrexate Effective?

Methotrexate with misoprostol is a very effective method of early pregnancy termination. Similar to mifepristone, early (i.e., up to 49 days LMP) methotrexate-induced abortions have effectiveness rates of greater than 90%.<sup>21</sup> Methotrexate is also effective for abortions after 49 days LMP.<sup>21, 44, 52</sup> Although some studies have shown slightly lower effectiveness rates using methotrexate after seven weeks LMP (e.g., 85%),<sup>21, 51, 52</sup> this may be due to differences between the regimens in timing of drug administration and the number of doses of misoprostol given, in addition to gestational age. Although the effectiveness of methotrexate/misoprostol is comparable to

mifepristone/misoprostol, methotrexate-induced abortion can take longer, ranging from one to five weeks.<sup>7, 44, 51, 53, 57</sup>

## Who May Provide Medical Abortion Using Methotrexate?

An individual provider's ability to prescribe methotrexate depends on the scope of his or her practice and whether there are administrative rules or specific state laws that regulate the prescription of methotrexate for abortion. Some states limit provision of abortion to physicians, and the limits and conditions of prescribing privileges (e.g., which drugs can be prescribed by which types of providers – physicians, registered nurse practitioners, certified physician assistants, etc.) differ from state to state.

In summary, medical abortion is both safe and effective. Medical abortion usually involves a combination of drugs, either mifepristone with misoprostol or methotrexate with misoprostol. Although mifepristone has been approved by the FDA specifically for early pregnancy termination, methotrexate is also used for medical abortion. In addition to being safe and effective, medical abortion has the potential to expand women's access to abortion services and give those who prefer it an alternative to surgical abortion. The potential of medical abortion to expand access and increase options is discussed in the following chapter.







## Access to Abortion

### The Obstacle: Access to Abortion is Limited

Many women in the U.S., especially those in rural areas, live in counties with no abortion provider. A decline in providers and other factors that limit women’s access to abortion are described below.

- The Number of Providers Trained in Performing Surgical Abortion is Low.** Training in abortion procedures has declined in part because fewer abortions are performed in hospital settings where the majority of residency training occurs. Although the percentage of programs offering training increased after the Accreditation Council for Graduate Medical Education began requiring abortion training as a part of OB/GYN residency training in 1996 (for residents and programs without moral or religious objections), a 1998 survey found only 46% of programs made first trimester abortion training a routine part of their program. Only 26% of programs reported all their residents received training. Although many programs say they offer optional off-site training in abortion procedures, the already overloaded OB/GYN resident is unlikely to take advantage of such an option.<sup>58</sup>
- Abortion Services are Distributed Unevenly.** In most states, over three-quarters of counties do not have an abortion provider, and the entire Midwestern U.S. lacks providers in 90% or more of its counties.<sup>2</sup> As a result, access to abortion is very limited for many women living in the U.S. According to recent data, the highest rates of abortion (number of abortions per 1,000 live births) are concentrated in the western U.S. (California, 38 abortions per 1,000 live births) and along the East Coast (Delaware, 30 per 1,000; New York, 35 per

1,000; Washington, D.C., 68 per 1,000). Relatively lower rates of abortion (fewer than 10 abortions per 1,000 live births) occur in the Midwest and the South.<sup>59, 60</sup> State abortion rates vary due to multiple factors (e.g., differential rates of pregnancy, differences in state laws), but the variation is also likely due to differences in the accessibility of abortion services.

- Anti-abortion Harassment Impacts Use of Abortion Services.** Most abortions are performed in specialty abortion clinics where at least half of all patient visits are for pregnancy termination services.<sup>60</sup> These facilities are the most likely to be targeted for anti-abortion harassment. Women who feel intimidated or threatened by anti-abortion harassment may be

### Incidents of Violence and Disruption Against Abortion Providers

	1985-1989	1990-1994	1995-2000
Picketing	580	6921	37,790
Bomb threats	196	74	223
Vandalism	174	341	324
Hate mail/harassing calls	166	1641	7149
Invasion	145	100	22
Death threats	43	155	112
Assault & battery	40	37	25
Arson	37	60	39
Attempted bomb/arson	26	27	16
Burglary	15	14	29
Bombing	6	4	11
Murder	0	5	2
Attempted murder	0	11	6
Kidnapping	0	0	1
Stalking*	–	210	222

\*Tabulation of stalking incidents began in 1993

Source: National Abortion Federation. Violence and disruption statistics: Incidents of violence and disruption against abortion providers. Washington, D.C.: NAF, 2000.

discouraged from seeking abortion services at these clinics. Studies show that women who come in contact with anti-abortion protestors view these encounters as adverse and tend to feel angry and intruded upon.<sup>61</sup> In places where these clinics are the sole providers of abortion services, anti-abortion harassment can, in effect, prevent women from accessing abortion services.

Anti-abortion harassment discourages some providers from offering abortion services. Fewer providers means women's access to abortion services is further limited. Harassment aimed at providers includes violence (e.g., murder and assault), threats of violence (e.g., attempted murder, bomb threats, stalking), and clinic blockades.<sup>62</sup> Providers may have difficulty hiring clinic staff because of the risk of violence or harassment. Even low level harassment has a dampening effect on the hiring of medical and nonmedical staff.<sup>61</sup> Providers may also face other barriers as a result of harassment, such as costs of increased security, increased insurance rates, and legal fees to fight harassment.

### **The Potential Solution: Medical Abortion Could Improve Women's Access to Abortion**

- **Medical Abortion Could Increase the Number of Abortion Providers.**

Increasing the number of providers has the potential to increase access to abortion services. Providers who have been afraid of being targeted by anti-abortion protestors may feel safer offering medical abortion because of its greater privacy. Prior to FDA approval many providers expressed interest in providing mifepristone-induced abortions should the approval be granted.<sup>63, 64</sup>

- **Medical Abortion Could Increase the Types of Providers.** Medical abortion is safely administered by practitioners in specialties outside of obstetrics/gynecology, such as family practice, as well as by nurse practitioners, nurse midwives, and physician assistants. Continuing this expansion to providers of different specialties and advanced practice clinicians could make abortion services more widely available.<sup>64-66</sup> There is nothing unique to medical abortion that is outside the scope and practice of advanced practice clinicians (e.g., pregnancy testing, counseling, estimating gestational age by exam and ultrasound, medical screening, administering medications, post-abortion follow-up care, performing uterine re-aspiration for incomplete abortion). However, the ability of advanced practice clinicians to offer medical abortion varies by state (see Chapter 4).

- **Medical Abortion Could Improve the Geographic Distribution of Abortion Providers/Services.** By providing medical abortion through advanced practice clinicians and those who previously did not offer surgical abortion, access to abortion services could expand into geographic areas where service provision is limited or entirely lacking. Women in non-metropolitan areas, rural areas, and in Midwestern and Southern states could see an increase in the number of abortion providers.

- **Medical Abortion Could Expand Abortion Services Beyond Abortion Clinics.** The majority of abortions are provided at specialty abortion clinics.<sup>2</sup> Medical abortion, however, could be made available in private medical offices. Including abortion services with other gynecological care ensures that women have access to coordinated and comprehensive health care.<sup>60</sup>

- **Medical Abortion Could Decrease Violence and Harassment of Patients, Providers, and Clinic Staff.** With medical abortion, women may no longer be limited to seeking care from a specialty abortion clinic with the potential for harassment by anti-abortion protesters. If the number and type of providers expands, it might be possible for many more women to go to private practice physicians to obtain medical abortions. The increase in privacy and confidentiality could mean less harassment of women seeking to have an abortion. If abortion services move into the practices of those providing more general reproductive health care, abortion providers and clinic staff may be less visible and identifiable. Less visibility could make it more difficult for abortion protesters to target those providing abortion services.

## Options in Abortion Methods

### The Obstacle: Limited Options for Abortion

Clinical abortion services in the U.S. have remained relatively unchanged for over a decade.<sup>67</sup> For example, women are usually advised to wait until at least six weeks gestation to schedule an abortion. Also, the same surgical techniques used for an abortion at 6-7 weeks gestation are also generally used at 11-12 weeks gestation. However, women who have had a choice of methods have reported higher levels of satisfaction with the abortion procedure, regardless of the method chosen.<sup>68</sup>

- **Women Need an Option That Can Be Used Early in Pregnancy.** As a general rule, surgical abortion is not performed earlier than six weeks since the last menstrual period (LMP). Medical abortion can be performed as soon as a woman knows

she is pregnant (as early as one week after fertilization)<sup>69</sup> and up to 63 days since LMP.<sup>30</sup> This is important because abortion is safest when used early in pregnancy (<13-14 weeks), with the lowest rates of complications occurring among women undergoing abortion at eight weeks LMP or less.<sup>70</sup> In addition, some women like early methods so they do not need to wait weeks to terminate a pregnancy.<sup>71</sup>

- **Women Need Abortion Options Appropriate to Their Life Circumstances.** Women need options that fit their personal circumstances.<sup>72</sup> Issues such as the direct and indirect costs involved in having an abortion (e.g., cost of the procedure itself, time lost from work), the availability of social support, the attitudes of intimate partners about abortion, personal religious and cultural beliefs, and phase of life (e.g., teenagers, young adult, and mid-life women) influence a woman's choice of abortion method. What a woman wants at one point in her life may be different from what she wants later in life, given the many ways in which women's lives change over time. Women need to be able to choose a method that is consistent with who they are and what their circumstances are at the time they are seeking an abortion.
- **Women Differ in Their Preference for Abortion Methods.** Women differ with respect for their preferences for certain characteristics of abortion methods.<sup>49, 72-77</sup> Some women prefer medical abortion because they say the experience feels more natural, is more private, and allows them more control over the experience. Other women prefer medical abortion because they prefer a method that can be used early in pregnancy or allows them to avoid surgery. Alternatively, some women prefer surgical abortion because they want anesthesia and a clinician in attendance. Some women also prefer sur-

gical abortion because it is quick and completed in one visit.

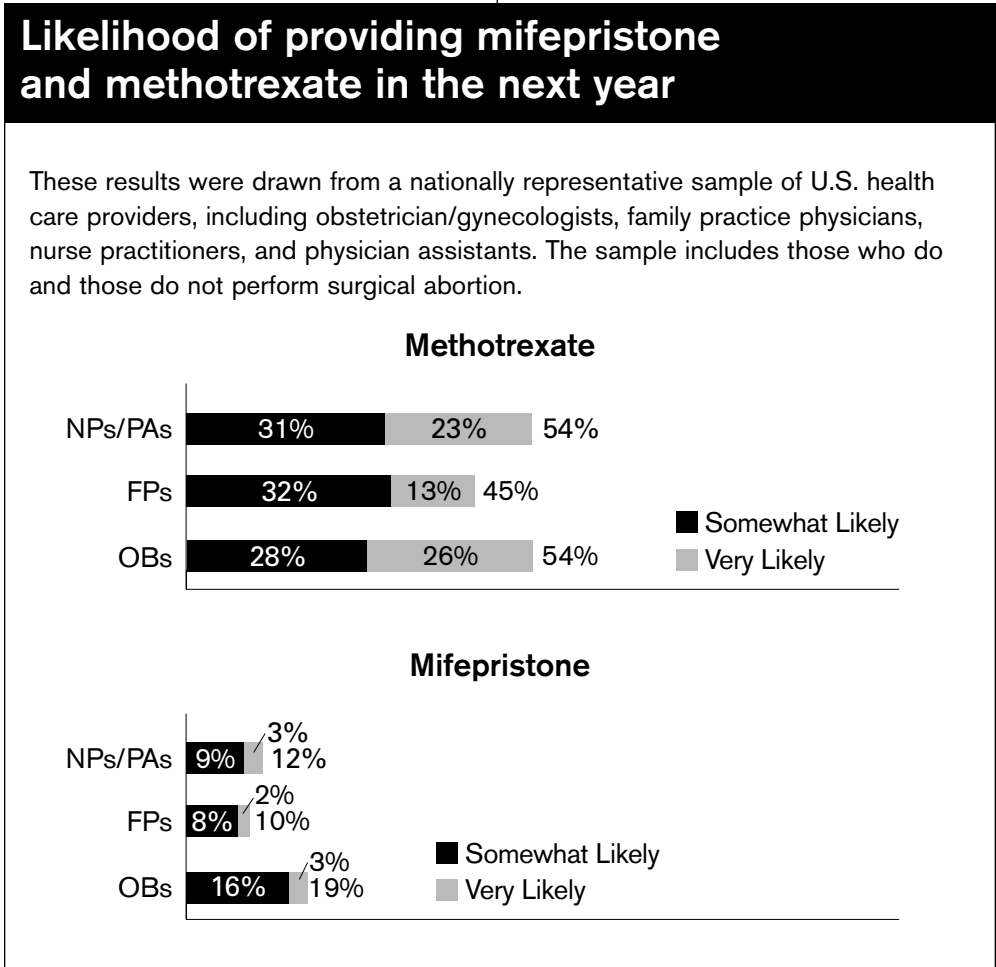
### The Potential Solution: Medical Abortion Offers Women Options in Abortion Methods

- Women Find Medical Abortion Acceptable.** In order for medical abortion to increase options for women, women must be willing to use it and find it acceptable. The majority of women who have used medical abortion say they were satisfied with the method. Studies have shown that more than 85% of women who had either a mifepristone- or methotrexate-induced abortion were

moderately or very satisfied with their medical abortion experience.<sup>22, 49, 55, 56, 73, 77, 78</sup>

- Medical Abortion Provides Women with a Choice of Abortion Method.** Until recently, the only option women in the U.S. had for terminating a pregnancy was a surgical abortion. Now women can choose between surgical and non-surgical methods of pregnancy termination. This is a major breakthrough in abortion care.

Offering women options means women can choose the method that is most suitable to their needs and life circumstances. Given a choice of abortion method, women are more satisfied with their abortion experience.<sup>68, 76</sup>



---

**A Women's Perspective: "Give women a choice. If they're gonna both [RU 486 and vacuum aspiration] be there, I mean, you can decide what's right for you at the time."**

Data Source: Harvey SM, Beckman LJ, Branch MR. The relationship of contextual factors to women's perceptions of medical abortion. *Health Care Women Int.* 2002;23(6-7):654-665.

---

- **Medical Abortion Offers Women an Option That Can Be Used Early in Pregnancy.** Early abortion means safer abortion. The longer a pregnancy progresses the greater the medical risks in

## What Women Say

"You have to process it through your own situation. Maybe you have economic problems or

Source: Harvey SM, Beckman LJ, Branch MR. The relationship of contextual factors to women's perceptions of medical abortion. *Health Care Women Int.* 2002;23(6-7):654-665.

strong religious feelings or whatever. I don't think the medical facts are the be all end all of the situation."

"I like the fact that you pass it yourself, which is good. It is basically a miscarriage. Instead of

Source: Harvey SM, Beckman LJ, Castle MA, Coeytaux F. Knowledge and perceptions of medical abortion among potential users. *Fam Plann Perspect.* 1995;27(5): 203-207.

having it sucked out of you, you pass it out yourself, which is, I'm sure, a little bit easier on your uterus . . ."

"...I feel like it's easier for a person who is a mother . . . it's easier to take say 2 hours in one day rather than to save 2 days and many hours in each of those days. Using [mifepristone]

Source: Harvey SM, Beckman LJ, Branch MR. The relationship of contextual factors to women's perceptions of medical abortion. *Health Care Women Int.* 2002;23(6-7):654-665.

takes more time than is necessary . . . I think [surgical abortion] is more convenient."

terminating the pregnancy.<sup>70</sup> Although surgical abortion can be performed safely at six weeks or less LMP,<sup>79</sup> one source says many providers wait until a woman is seven weeks LMP to schedule an abortion.<sup>47</sup> Medical abortion is a safe method that can be used as soon as a pregnancy is confirmed by clinical exam, a pregnancy test, or ultrasound examination.<sup>47, 69</sup> Some providers and clinics require visualization of a gestational sac on ultrasound prior to performing an abortion;<sup>80</sup> the gestational sac becomes visible at approximately 35 days LMP.<sup>81</sup>

- **Providers Find Medical Abortion Acceptable.** Because medical abortion is a relatively new procedure in the U.S., there are few surveys of medical abortion providers. The available evidence generally indicates that providers have positive attitudes regarding medical abortion.<sup>64, 65, 82-87</sup> Medical abortion providers report that they like mifepristone and methotrexate because both are safe and effective in terminating early pregnancy. Many providers also like being able to offer women a choice of abortion methods.<sup>65, 88, 83</sup> These providers believe that giving women a choice increases the quality of care that women receive and gives them greater satisfaction.

In summary, medical abortion has the potential to increase access to abortion services in the U.S. and provide women with an alternative to surgical abortion. However, neither

**A Provider’s Perspective: “I am really pleased with [methotrexate] . . . I like that the woman is a participant in the procedure and she has control over it. Not like surgery where the woman is just a passive observer having something done to her body. I think it results in women who are ultimately more satisfied with their decision since they were part of the process.”**

Data source: Harvey SM, Beckman LJ, Satre SJ. Experiences and satisfaction with providing methotrexate-induced abortions among US providers. *JAMWA*. 2000;55(3 Supp):S161-163.

the potential of medical abortion to improve the lives of women nor its proven safety and effectiveness have ensured medical abortion’s availability. In the following chapter,

we discuss the role of politics and restrictive legislation on abortion practice, and what the impact of these may be on the practice of medical abortion.

## Acceptability of Mifepristone and Methotrexate to U.S. Women

Author/s & Year	Sample	% that found the method satisfactory	% that would choose the method again	% that would recommend the method to others
Schaff et al., 1999	933 women	94%	87%	85%
Winikoff et al., 1998	2121 women	88%	92%	96%
Beckman & Harvey, 1997	262 women	89%	87%	94%
Author/s & Year	Sample	% that found the method satisfactory	% that would choose the method again	% that would recommend the method to others
Harvey, Beckman, & Satre, 1999	186 women	82%	93%	78%
Wiebe, 1997	116 women	Not reported	Not reported	84%
Crenin & Park, 1995	86 women	79%	89%	Not reported

Source: Koenig JD, Tapias MP, Hoff T, Stewart F. Are US health professionals more likely to prescribe mifepristone or methotrexate?. *JAMWA*. 2000;55(3 Supp):S155-160.

## Past Research on Health Care Providers' Knowledge, Attitudes, and Practices Regarding Mifepristone and Methotrexate.

Authors	Date	Sample	Relevant Findings
Ellertson, C., et al., 1999	1995-96	Interviews: n=78, focus groups: n=18 providers (physicians, midlevel providers, counselors) from 17 sites	Providers reported being generally satisfied with mifepristone. Most thought midlevel providers could perform mifepristone abortions with physician backup. Staff at all but one site want to offer mifepristone if approved by the FDA.
Harvey, Beckman, & Satre, 2000	1997	N=76 providers from 17 sites offering methotrexate abortions (physicians, midlevel providers, administrators, counselors)	80% were satisfied or extremely satisfied with methotrexate. The mean satisfaction rating was 3.9 on a scale from 1 to 5. No physician or midlevel provider rated satisfaction as less than a 3. Five of the 12 respondents who voluntarily mentioned mifepristone had a clear preference for mifepristone over methotrexate.
Heilig, 1992	1991	N=466 random sample of OBs in California	48% had followed the RU-486 story "closely" and 45% followed it "somewhat closely." 14% were opposed to abortion and wouldn't use RU-486 if available. 69% thought RU-486 should be made available now to patients for abortion. 91% of those who currently provide abortions (n=255) would use RU-486. 32% of those who currently do not provide abortions (n=209) would use RU-486.
Joffe, 1999	1996	N=25 National Abortion Federation members (physicians, midlevel providers, counselors)	Providers who performed mifepristone and/or methotrexate abortions were generally satisfied with the process. All thought midlevel providers could perform medical abortions. Providers' worst fears at the outset were not realized (patient going to emergency room with hemorrhaging or patient not returning for required additional visits). Some providers saw the need for dating pregnancies (using ultrasound machines) as an obstacle for providers who are not surgical abortion providers.
McKee & Adams, 1994	1991	N=1208 nurse-midwives	57% would want authority to prescribe RU-486 if approved by the FDA. 25% would incorporate abortion procedures into their own practices, if allowed. 19% would perform abortions in the an abortion clinic, if allowed. 52% would vote anonymously in favor of allowing nurse-midwives to perform abortions.
Miller, Miller, & Pinkston Koenigs, 1998	1996	N=668 physician members of the Society for Adolescent Medicine	96% agreed that abortion should be available to pregnant adolescents under some or all circumstances. 42% would prescribe methotrexate or RU-486 for abortion if FDA-approved and physician training was available; 34% were unsure. 54% believed that if medical abortion becomes routinely available in the United States, primary care physicians should be allowed to perform them.
Rosenblatt, Mattis, & Hart, 1995	1994	N=138 providers in rural Idaho (FPs, OBs, general surgeons)	26% said they would definitely prescribe RU-486 if it became available; 35% were unsure. About half of those morally opposed to abortion said they would not refer their patients to another provider for RU-486.
Rosenblatt, Robinson, Larson, & Dobie, 1999	1996-97	N=286 first- and second-year medical students at University of Washington	41% believed that RU-486 should be available under "most circumstances," and 44% believed that it should be available "with limitations." 62% expected that they would provide RU-486 in future practice. Female students (69%) were more likely to expect to provide RU-486.



# Access to Medical Abortion in the United States: What Are the **Political and Legal Barriers?**

Why is it that mifepristone, which has been used safely and effectively by millions of women worldwide, is so hotly debated in the U.S.? Why has this drug had such difficulty coming to market in the U.S. despite the consistent findings from research on its safety, effectiveness, and acceptability? It's simple: the underlying objections to mifepristone are not about the safety and effectiveness of this drug, although it has often been described incorrectly as dangerous by anti-abortion advocates.<sup>89</sup> At their core, objections to mifepristone are objections to abortion itself. Because the right to abortion continues to be debated so intensely in the U.S., mifepristone – a safe and effective abortifacient – has taken two decades to reach U.S. women. Abortion politics have turned the rather straightforward study and approval of this regimen into a prolonged process, vulnerable to shifts in the political climate. Below we examine the role of politics in abortion policy and legislation and how specific laws and policies may restrict access to medical abortion.

## **What Is the Role of Politics in Medical Abortion Legislation and Policy?**

It is not yet clear whether the practice of medical abortion will be subject to the same policies as surgical abortion, however some policy makers have targeted medical abortion specifically. An example of the role politics plays in medical abortion policy is the proposal of the “RU-486 Patient Health and Safety Protection Act” (Legislative bills S251/HR482). First introduced in the U.S. House and Senate in October 2000, this bill would have limited access to mifepristone by imposing restrictions that, according to the FDA and numerous medical groups, are unnecessary and do not add to the safety of mifepristone. These proposed restrictions include requiring providers of mifepristone/misoprostol-induced abortion to be trained in surgical abortion, to be certified in ultrasound dating of pregnancy, to complete a training program regarding the prescription of mifepristone, and to have admitting privileges within a one-hour distance from their principal medical office.<sup>90</sup> It is important to note that the current law and standard of

care in the U.S. does not mandate that a health care practitioner who provides prenatal care be capable of handling complications from an incomplete abortion or ectopic pregnancy. As such, the requirement that providers of mifepristone be able to handle these complications singles out these providers for more stringent regulations than is standard for medical practice in the U.S.

## What Are the Political Strategies Used to Limit Medical Abortion?

Political attacks upon the safety of mifepristone/misoprostol have been the primary mechanism to limit access to medical abortion. Methotrexate has received less attention, perhaps due in part to its off-label status. The arguments against mifepristone/misoprostol have focused on essentially three basic myths: 1) mifepristone is a risky medication which poses serious health risks to women; 2) mifepristone was rushed through the FDA approval process and did not receive a thorough review of its safety and effectiveness; and 3) misoprostol is dangerous and poses health risks to pregnant women. These myths are refuted below.

### Myth #1: Mifepristone is a risky drug

Anti-choice advocates have repeatedly suggested that mifepristone poses serious health risks to women and that its use should be limited. They have asserted that mifepristone is a “dangerous drug” which creates serious and potentially fatal side effects.<sup>89, 91</sup> However, a multitude of studies conducted in the U.S. and abroad which have rigorously studied the safety and effectiveness of mifepristone have demonstrated otherwise (see Chapter 2). The effectiveness of this

drug is precisely what abortion opponents find objectionable.<sup>90</sup>

### Myth #2: Mifepristone was rushed through the FDA approval process

Anti-choice advocates claim that mifepristone was hurriedly approved without ensuring health protections for women who would use it.<sup>92</sup> Mifepristone was, in fact, approved under a special provision of the FDA review process known as “Subpart H”.<sup>93</sup> Although Subpart H does have a provision for accelerated review, it can also be used for the sole purpose of putting restrictions on drug distribution. In the case of mifepristone, Subpart H was *not* used to expedite the review process but only to place restrictions on mifepristone’s distribution (for the details of these restrictions see Chapter 2). As a part of the approval process, the FDA reviewed data from U. S. clinical trials of mifepristone involving over 2,000 women, as well as numerous European studies involving tens of thousands of women, which demonstrated both the safety and effectiveness of this medication for early pregnancy termination.

### Myth #3: Misoprostol is dangerous to pregnant women

Myths about misoprostol, the drug used in conjunction with both mifepristone and methotrexate, have also circulated. Without misoprostol as a part of the regimen, the effectiveness of both mifepristone and methotrexate is significantly decreased. Therefore, the availability of misoprostol is crucial for the practice of medical abortion. One myth about misoprostol is that it is dangerous to women. The story behind this particular myth is told below.

- **The Searle Letter.** In August 2000, G. D. Searle & Co., the pharmaceutical manufacturer of the drug misoprostol (marketed as Cytotec®), issued a letter in which it warned physicians that misoprostol should not be used with pregnant women because it can cause abortion.<sup>94</sup> In addition, Searle argued that the risks to a developing fetus exposed to misoprostol when used for labor induction or cervical ripening (the thinning, softening, and opening of the cervix) had not been determined. The letter was immediately picked up by anti-choice advocates, including members of Congress, who reported that misoprostol was dangerous and could cause a woman's uterus to "explode".<sup>95</sup> Thus, the Searle letter was used to argue against medical abortion, suggesting that it is dangerous and threatens the health of women in the U.S.

- **The Medical Community Responds.** The American College of Obstetrics and Gynecology (ACOG), the primary professional organization of physicians engaged in the science and practice of women's reproductive health care in the U.S., responded to the Searle letter. In 1999 ACOG had carried out its own review of the many published studies on the use of misoprostol for labor induction and concluded that misoprostol was safe and effective for inducing labor.<sup>96</sup> In October 2000 ACOG sent the FDA an updated report of the research data on misoprostol, including studies on its use for medical abortion. In a statement which accompanied the report,<sup>97, 98</sup> ACOG noted that the serious side effects cited in the Searle letter involved higher doses of misoprostol and were relatively rare. ACOG also highlighted the strong safety record of misoprostol when used appropriately and presented guidelines to minimize the potential for adverse events,

although adverse events were already rare. ACOG also questioned the timing of the Searle letter which had been issued just a few weeks prior to the FDA approval of mifepristone. ACOG clarified the important role of misoprostol as a reproductive health drug beyond its role as an abortifacient and included a point-by-point refutation of proposed FDA restrictions for the mifepristone/misoprostol regimen put forth by anti-abortion Congressional representatives. The FDA ultimately rejected these restrictions.

- **FDA Gives Misoprostol A New Label.** In April 2002, the FDA announced that it changed the label for misoprostol (known by the brand name Cytotec®).<sup>99</sup> Misoprostol is sometimes used to reduce the risk of stomach ulcers. In recognition of this, the new label says pregnant

### Excerpt from ACOG letter

"...The American College of Obstetricians and Gynecologists (ACOG) is concerned by the content, timing, and tone of [the Searle] letter. Given that misoprostol is commonly employed in conjunction with mifepristone (RU 486) to achieve nonsurgical early pregnancy terminations, the arrival of the Searle letter within weeks of the U.S. Food and Drug Administration's (FDA's) approval of mifepristone could limit the use of the new option for reproductive choice. Also, although the letter correctly points out the potentially serious, but relatively rare, risks of misoprostol when employed for cervical ripening and labor induction, it fails to comment on the extensive clinical experience with this agent and the large body of published reports supporting its safety and efficacy when used appropriately."

*from a the ACOG letter by Stanley Zinberg, MD, to Janet Woodcock, MD, Director of the FDA, October 26, 2000.*

women should not use the drug for this purpose. The Searle label had stated that pregnant women should not take the drug under any circumstances. The FDA said that it clarified the warning to reflect that “the drug has a recognized use by obstetricians and gynecologists to induce labor, delivery and is part of the FDA-approved regimen for use with mifepristone to induce abortion.”<sup>99</sup>

## What Are the Laws and Policies That May Restrict Access to Medical Abortion?

Laws governing abortion, which may also apply to medical abortion, vary widely from state to state. However, several state laws deserve particular attention because they are likely to be applied to medical abortion practice. Although not a comprehensive review of state laws, the paragraphs below describe several types of legal statutes which have become common across the U.S. and that may impact the availability of medical abortion services. Anyone wishing to determine legal issues pertaining to a particular state should check the laws governing that state.

### Laws That Restrict the Provision of Medical Abortion

#### Physician-Only Laws

Most states have laws which restrict the provision of abortion to licensed physicians. One survey found that only six states (Arizona, Kansas, New Hampshire, Oregon, Vermont, and West Virginia) did *not* have such laws.<sup>100</sup> In some states, however, these laws may not preclude non-physicians from performing medical abortion because their

statutes have defined abortion very narrowly (e.g., as a surgical procedure). In other states, such as New York, Montana, and Rhode Island, rulings by administrative agencies or state courts supercede physician-only laws and permit certain non-physician practitioners to provide medical and/or surgical abortions.<sup>101-104</sup> In addition, if laws are interpreted consistent with the standard of care (i.e., standard medical practice), physicians may delegate tasks to “qualified agents” such as physician assistants. Such a legal interpretation may allow for the provision of medical abortion by advanced practice clinicians working under the supervision of a physician.<sup>105, 106</sup>

#### Dispensing Authority Laws

Physicians generally have authority to prescribe any FDA-approved drug, although some states have enacted restrictions. In states with restrictive dispensing authority laws, dispensing drugs for medical abortion may be limited to licensed physicians.<sup>100, 106, 107</sup> Several states have laws granting dispensing authority to advanced practice clinicians (i.e., nurse practitioners, physician assistants), either as independent practitioners, under the supervision of a licensed physician, or under collaborative prescribing agreements with physicians. By restricting dispensing authority, these laws directly impact the ability of advanced practice clinicians to engage in the provision of medical abortion.

#### TRAP Laws

Targeted Regulation of Abortion Providers (TRAP) laws consist of laws that single out abortion providers and facilities where abortions are performed and impose on them regulations not applied to other physicians or outpatient clinics. For example, TRAP laws can restrict abortion practice when they

require special licensing and/or physical plant specifications that are burdensome to meet. Requirements vary widely by state and can include licensing of the abortion provider, state inspections of the medical facility, room air exchange rates, and minimum space requirements surrounding beds in recovery areas.<sup>100, 106, 108</sup>

Requirements sometimes are applied only to those facilities that provide a certain volume of abortion services.<sup>106</sup> For new providers of abortion in states with requirements targeting only high volume abortion facilities, the existing TRAP laws may not apply if the facility only performs medical abortion on an occasional basis as a part of a general health care practice. However, for providers who perform higher numbers of medical abortions, attempts may be made to apply these statutes to medical abortion as well.<sup>105</sup>

### **Laws Regarding Examination and Disposal of Fetal Tissue**

Several states have laws that require the examination of the aborted tissue by the physician performing the abortion and/or a pathologist. In a review of related laws,<sup>106</sup> 13 states had fetal tissue examination laws which on their face may be applicable to medical abortion. The person designated to examine the tissue varies from state to state, with some laws specifying their applicability only to abortions performed in certain types of facilities. Many states also have laws about the disposal of fetal tissue. These laws vary widely by state and may require burial, cremation, or incineration. The applicability of these laws to medical abortion is unclear and to date they have not posed a barrier to medical abortion practice. Compliance with a fetal tissue examination or disposal law would obviously be difficult for a medical abortion provider if the

woman expels the tissue some place other than the provider's office.<sup>100, 106</sup>

### **Laws That Restrict Women From Obtaining Medical Abortion**

Abortion-related laws that on their face appear to protect women's health and safety may, in practice, result in delaying women from obtaining abortion. By delaying abortion, these laws may actually increase health risks to women.

### **Informed Consent Laws**

The term *informed consent* refers to ensuring that a patient understands what is involved in a treatment or procedure, the potential risks and benefits, and any available alternatives. This process ensures that the patient has the information necessary to make an informed choice about undergoing the treatment or procedure. Informed consent is important to the health and safety of women obtaining an abortion. Informed consent consists of a full description of the procedure involved, the potential risks, and the treatment alternatives. However, informed consent laws *written specifically for abortion* require adding biased language and/or procedures to the informed consent process. Many states have laws which specify in the consent form scripted language unrelated to the risks, benefits, or alternative treatments for pregnancy termination, and in essence act to discourage women from having an abortion.<sup>100</sup> Discouraging a woman from having an abortion is outside the scope of informed consent and does nothing to improve a woman's understanding of the risks of a given abortion procedure and the alternative procedures that might be used. Furthermore, state-mandated informed consent procedures can also act as barriers to

abortion. In some states this state-mandated information must be provided by the physician in person; in others it can be delegated by the physician to other staff or provided via written materials which can be mailed.<sup>107</sup>

<sup>109</sup> The practical results of this type of legislation are twofold: 1) the language in state-scripted informed consent compels providers to discourage women from choosing abortion, and 2) the added consent procedures cause delays in access to abortion. Thus, informed consent legislation written specifically for abortion makes the consent process biased and extremely cumbersome.

### **Waiting Period Laws**

Waiting period laws require a delay of a specified length between the request for an abortion and the provision of an abortion. The length varies from state to state (e.g., Indiana, 18 hours; Tennessee, 48-72 hours) with the most common waiting period being 24 hours.<sup>109</sup> In some states, the waiting period begins after state-mandated in-person abortion counseling has been performed.<sup>107, 109</sup> Waiting period laws pose a significant barrier to women seeking medical abortion because they delay the initiation of abortion. Medical abortion is a regimen that is most effective early in pregnancy and therefore needs to be done in a timely manner. The delays introduced by waiting periods may make medical abortion impossible.

### **Parental Involvement Laws**

Many states require some sort of parental involvement when a minor seeks an abortion.<sup>106</sup> At least one state (Tennessee) has specifically indicated the applicability of parental notification to medical abortion.<sup>110</sup> Parental involvement laws can delay access to abortion. A young woman, for example, may put off her decision while struggling

with how to tell her parents. In addition, judicial bypass – whereby a young woman may seek permission for abortion from a judge rather than from one or both parents – also takes time. The delay introduced by these parental notification laws is significant given that medical abortion can only be performed early in pregnancy.

### **Public Funding Issues**

All states are prevented from providing federal Medicaid funding for abortion for low-income women except in cases of rape, incest, or when the pregnant woman's life is endangered (a provision known as “the Hyde Amendment”).<sup>100, 107</sup> Some states use state money to provide funding for abortions for low-income women, either voluntarily or when state courts have interpreted their respective constitutions broadly on the issue of reproductive health rights. On March 30, 2001 the U.S. Department of Health and Human Services notified state Medicaid directors that the federal Medicaid funding restrictions for surgical abortion also apply to medical abortion.<sup>111</sup> In addition to funding the procedure, use of public facilities has also been banned in state laws. In 1989 the U. S. Supreme Court upheld a Missouri state law which banned the use of public facilities for the provision of abortion except to save the life of the woman. In some states, courts have struck down efforts to prevent the use of public or quasi-public facilities for the provision of abortion services.<sup>107</sup>

## **What Are the Challenges Ahead?**

In the coming months and years, several legal and political issues that may have an impact on access to and provision of med-

ical abortion services will be debated. Some of these issues are described below.

### FDA Approval of Mifepristone

The FDA may be pressured by anti-choice advocates to re-examine and possibly overturn its approval of mifepristone, or at a minimum to increase the restrictions placed on its provision. A new commissioner of the FDA is appointed by each new administration. Future commissioners may consider revisiting the approval of mifepristone. Whether or not the FDA will yield to political pressures to undo its prior approval of mifepristone is unclear.

### Proposed Legislation to Limit the Use of Medical Abortion

Several types of legislative bills and other policy changes have been proposed in both federal and state legislative bodies that would affect the availability of medical abortion. These include banning drugs used in medical abortion regimens and refusal (“conscience”) clauses. These types of policies and their relevance to medical abortion access are described below.

- **Banning Drugs Used in Medical Abortion Regimens.** In some states there have been attempts to ban drugs used in medical abortion regimens. In Michigan such an attempt was successfully challenged. The Michigan bill would have banned any drug for abortion that was not FDA-approved for a medically-induced abortion by banning such drugs from state-mandated abortion counseling.<sup>107, 112</sup> Although mifepristone and misoprostol have since been approved by the FDA for use in medical abortion, methotrexate is still used off-

label for medical abortion and would have been banned by this statute.

- **Refusal Clauses.** Refusal clauses allow individual health care professionals to refuse to provide services to which they say they have moral objections, such as emergency contraception or abortion. For example, this type of legislation has been introduced in Kentucky<sup>113</sup> to allow pharmacists to refuse to fill prescriptions for medications “whose primary purpose is to terminate a pregnancy.” Currently, mifepristone is distributed only to physicians who, in turn, dispense the drug to patients (see Chapter 2), therefore this type of legislation is unlikely to impact access to mifepristone. However, should misoprostol be prescribed for women to take at home, or if the FDA regimen were changed to allow for provision of mifepristone through pharmacies, this type of legislation could restrict women’s access to medical abortion.

In summary, political and legal barriers continue to threaten women’s access to medical abortion services in the U.S. The main anti-choice argument against medical abortion is that mifepristone is unsafe. However, this accusation is clearly refuted by the wealth of available scientific studies that document its safety and effectiveness. A common mechanism for limiting access to medical abortion is legislation introduced at both the federal and state levels. One of the primary ways in which laws impact medical abortion is by creating delays in initiating an abortion (e.g., waiting laws, informed consent laws, parental notification laws). Clear, understandable information about the safety and effectiveness of the two main medical abortion regimens (mifepristone/misoprostol, methotrexate/misoprostol) is crucial in this ongoing public debate. Next, we turn our attention to barriers faced by health care providers in the provision of medical abortion services.





# Access to Medical Abortion in the United States: **What Are the Barriers** for Medical Abortion Providers?

The practical realities of providing a new medical technology to patients can be barriers to service provision. With medical abortion services, even surgical abortion providers must learn new protocols, train staff, and adjust their practices to the new service they are providing. More information is needed regarding obstacles to initiating medical abortion services as well as reasons why some providers decide not to offer medical abortion. A study of abortion providers conducted in 2000 (prior to the FDA approval of mifepristone) reveals that, although there were many who experienced more than one major obstacle to establishing medical abortion services, most of those obstacles diminished or disappeared once services were in place.<sup>114</sup> However, some obstacles to the provision of medical abortion remained. Barriers encountered by providers initiating medical abortion services are described below.

## **Additional Staff Training and Time Needed to Counsel Women Regarding the Medical Abortion Regimen**

Increased time for counseling patients and the need for training in medical abortion counseling are commonly reported obsta-

cles in establishing medical abortion services.<sup>83, 88, 114</sup> However, once begun, some abortion providers also reported that service provision became routine after relatively few procedures.<sup>114</sup> This finding suggests that although training staff in medical abortion counseling and the increased time needed to perform medical abortion counseling were obstacles, these aspects of service provision were less problematic once clinicians and staff became accustomed to the new procedures.

## **Multiple Office Visits for Administration of Medical Abortion**

Because the FDA-approved regimen requires in-office administration of both mifepristone and misoprostol, a mifepristone-induced abortion done according to this regimen takes a minimum of three office visits as compared to the two recommended for surgical abortion. While the FDA regimen requires in-office administration of misoprostol, there are many studies which have demonstrated the safety of home administration.<sup>75, 115, 116</sup> Abortion providers cited the logistics of multiple office visits as one of the main obstacles to initiating abortion

services.<sup>88, 114</sup> Simplifying the medical abortion regimen by reducing the number of visits (for example by allowing patients to administer the misoprostol at home) could eliminate this obstacle. There is anecdotal evidence that many providers are utilizing evidence-based regimens which eliminate the second clinic visit.<sup>117</sup> Eliminating the second visit can be done without compromising safety or effectiveness.<sup>36, 118</sup> However, the post-treatment examination is necessary to confirm completion of a medical abortion. If a pregnancy continues after either a mifepristone/misoprostol or a methotrexate/misoprostol abortion, birth defects are possible.

## Ultrasound Examination

Neither the FDA requirements nor the Prescriber’s Agreement stipulates ultrasound use or training as a requirement for prescribing mifepristone. However, some providers confirm an intrauterine pregnancy by ultrasound to avoid missing an ectopic pregnancy.<sup>119</sup> Providers have cited additional

staff training in vaginal ultrasound as an obstacle to providing medical abortion services.<sup>83, 114</sup> Anti-choice legislators have proposed requiring abortion providers to be certified in ultrasound evaluation as a condition for prescribing mifepristone,<sup>90</sup> and similar proposals aim to restrict who may perform the ultrasound examinations. Training needs and restrictions on the performance of ultrasonic examinations could be significant obstacles to the provision of medical abortion.

## Access to Surgical Back-up for Incomplete Medical Abortion

Providers of medical abortion need to be able to provide surgical abortion or have a referral plan for that service if a medical abortion is incomplete. The availability of back-up for those rare cases of complications following medical abortion is important for protecting women’s health and safety. Back-up arrangements are consistent

### Top 5 Major Obstacles to Initiating Medical Abortion Services

Obstacle	N*	%**
Time for counseling	18	72
Training in counseling	16	64
Logistics of multiple visits	13	52
Training in vaginal ultrasound	10	40
Training in medical abortion procedure	9	36

\* Total N=41

\*\* Total does not equal 100% because subjects were permitted to name multiple obstacles.

*Data Source: Benson J, Clark KA, Gerhardt A, Randall L, Dudley S. Early abortion services in the United States: Ensuring service availability, remaining on the cutting edge of technology and responding to client demand-Final study report. Chapel Hill, NC: Ipas; 2001.*

with the American College of Obstetrics and Gynecology’s guidelines for provision of medical abortion<sup>9</sup> and is an FDA requirement for providing mifepristone.<sup>17</sup> Most providers of women’s health care already have referral plans for their patients who experience a spontaneous abortion (i.e., miscarriage) and need surgical completion. Nonetheless, securing back-up for medical abortion may present difficulties for some providers. Providers in rural areas, in particular, may have difficulty finding access to surgical back-up. Although *surgical back-up* usually refers to electric vacuum aspiration, manual vacuum aspiration (MVA) is another surgical abortion method which may be a better option for some providers because it is an easy-to-learn method and the instruments are inexpensive and portable. MVA has been used for many years throughout the world for spontaneous and incomplete first trimester abortion and is as safe and effective as electric vacuum aspiration.<sup>120</sup> Because the provider uses a handheld syringe as a source of suction, MVA can be used in many different settings, including those without the equipment necessary for electric vacuum aspiration.<sup>121</sup>

## Malpractice Insurance Issues

Clinicians are required to notify their malpractice insurance carriers of any significant additions or changes to their medical practice. New providers of medical abortion who have not already been providing surgical abortion will most likely have to report the addition of medical abortion. Not all malpractice insurance companies cover abortion services, thus, some providers may need to change carriers.<sup>100</sup> In some cases, adding medical abortion services may result in increased malpractice insurance premiums, potentially discouraging providers from adding this service to their practice.

## Third Party Reimbursement

Reimbursement from third party payers (i.e., Medicaid and commercial health plans) is a potential barrier particularly for primary care providers because their reimbursement rates for office visits tend to be lower than those of specialists (such as obstetrician/

### Top 5 Advantages to Offering Medical Abortion Services

Advantage	N*	%**
Clients want services	26	100
Staff likes new skills	24	92
Cutting edge of technology	23	88
Less stress for clients	21	84
Staff prefers earlier services	14	54

\* Total N=41

\*\* Total does not equal 100% because subjects were permitted to name multiple obstacles.

Data Source: Benson J, Clark KA, Gerhardt A, Randall L, Dudley S. Early abortion services in the United States: Ensuring service availability, remaining on the cutting edge of technology and responding to client demand-Final study report. Chapel Hill, NC: Ipas; 2001.

gynecologists) and may be insufficient to recover costs. Inadequate reimbursement may discourage primary care practitioners from adding medical abortion services to their medical practice.<sup>122, 123</sup>

## **Additional Obstacles for New Abortion Providers**

Compared to those who are already providing surgical abortion, practitioners who have never before offered abortion services may have additional obstacles because they may need to address general issues related to the provision of abortion services for the first time. These providers will need to train staff in abortion counseling, establish informed consent procedures and forms, learn about and establish procedures to comply with state laws regarding abortion practice, buy ultrasound equipment and obtain training in its use, establish fees for medical abortion services, and arrange for surgical back-up. In addition, the potential barriers of increased malpractice insurance premiums and third

party reimbursement are relevant to new abortion providers as well.

New practitioners may also have a variety of concerns about adding medical abortion services, including reactions from their colleagues, staff, family members, and community, as well as reactions of board members at hospitals where they have admitting privileges.<sup>124</sup> Taken together, the practical realities of setting up a new service and the political and personal costs of becoming an abortion provider may discourage some providers from initiating medical abortion services.

In summary, health care providers who choose to offer medical abortion services as part of their practice may encounter the same obstacles as they do when offering any new medical technology, such as additional training for themselves and their staff. However, other obstacles are unique to medical abortion, including the time associated with multiple office visits and financial considerations associated with malpractice insurance and third party reimbursement. In the following chapter, we outline recommendations for making medical abortion easier to provide and more accessible to women.

# Moving Forward

Medical abortion represents a significant advance in abortion practice. Until recently, surgical abortion was the only type of abortion available to women seeking early pregnancy termination. Now women can choose between surgical and medical abortion methods. Whereas access to surgical abortion has become increasingly restricted, especially for women living in rural areas, medical abortion has the potential to increase the number, types, and geographic distribution of abortion providers and reduce other barriers to access.

Medical abortion could change the landscape of abortion practice in the United States. If institutional and governmental decisions were based solely on scientific knowledge and consideration of women's health, medical abortion already would be widely available and more commonly used. However, other factors influence, and at times overwhelm, legislative and policy-making processes in the U.S. As a consequence, the laws, rules, and operational and judicial decisions that constitute abortion policy (as well as the private policies of hospitals and other health care organizations) are subject to political bargaining, ideological biases, and the preferences of powerful interest groups.

In the previous chapters, we have examined some of the barriers to the provision of and access to medical abortion in the

U.S. In this chapter, we present recommendations for policymakers and legislators aimed at increasing the availability of medical abortion.

## Recommendations

### Increase public awareness of the science and policies regarding medical abortion

The following recommendations are intended to correct misinformation about medical abortion, and to increase public awareness and understanding of the safety and effectiveness of medical abortion as demonstrated by medical and public health research.

- Support the development of national media campaigns to inform women about the availability, safety, and effectiveness of medical abortion.
- Support the availability of information regarding medical abortion in public clinics and health facilities, and publicly funded outreach programs.

- Provide the public with critical analysis of the impact of changes in laws and policy upon the availability of medical abortion.

### **Base policy decisions on the public health science of medical abortion**

The following recommendations are intended to ensure that policy decisions at all levels of government are made in the interest of women’s health.

- Develop policy statements based on scientific research that include the positions of leading professional organizations (e.g., American College of Obstetrics and Gynecology, American Medical Women’s Association, and the American Public Health Association).
- Rely on public health and medical research findings when developing and evaluating laws that could affect the availability of medical abortion.

### **Increase types of providers who perform medical abortion**

The following recommendations are intended to increase the types of providers who perform medical abortion by expanding the practice to advanced practice clinicians (i.e., certified nurse-midwives, nurse practitioners, and physician assistants).

- Oppose laws that bar advanced practice clinicians from practicing medical abortion, such as physician-only laws and laws that restrict prescriptive authority.

- Develop and support programs that provide education and training for advanced practice clinicians in medical abortion regimens.
- Urge professional organizations to develop and offer training, workshops, and other necessary support to advanced practice clinicians who want to provide medical abortion services.
- Support policies that require training in medical abortion in schools of nursing.

### **Increase the number of physicians who perform medical abortion**

The following recommendations are intended to increase the number of physicians who provide medical abortion services and enhance providers’ ability to provide medical abortion services.

- Develop and support policies that require training in medical abortion in medical schools.
- Support laws and policies that assist physicians who do not provide abortion, especially gynecologists and family practitioners, in adding medical abortion to their practices.
- Connect physicians with existing resources for the purposes of medical abortion training and support (e.g., National Abortion Federation and The Abortion Access Project).
- Promote and support expansion of FDA-approved medical abortion regimens to include other evidence-based regimens that have comparable or superior effec-

tiveness and side effects profiles (e.g., methotrexate regimens, home administration of misoprostol, vaginal administration of misoprostol, changes in dosage, and timing of administration of medical abortifacients).

- Oppose laws and policies that add legal barriers to medical abortion practice, such as TRAP laws, public funding restrictions, and laws which attempt to effectively limit providers to use of the FDA approved regimen (see Chapter 3 “Banning Drugs Used in Medical Abortion Regimens”).

### **Increase the number and types of health care settings in which medical abortion is provided**

The following recommendations are intended to increase the number and types of health care settings in which medical abortion is provided, thereby increasing access for many women and their choice of abortion method.

- Overturn and oppose laws that place unnecessary restrictions on facilities in which abortions are performed (i.e., TRAP laws).
- Support laws and policies that encourage providers to offer medical abortion services in the same facilities as other reproductive health care.
- Develop and promote incentive programs to encourage and enable providers to practice medical abortion in rural areas.

### **Increase access by making it easier for women to obtain medical abortion**

The following recommendations are intended to increase women’s access to medical abortion.

- Overturn and oppose laws and other policies that unnecessarily complicate and delay the process of obtaining an abortion, such as informed consent laws that introduce delays in abortion care, mandatory waiting period laws, and parental involvement laws.
- Reform the federal law that prohibits states from using federal Medicaid money to fund abortions for low-income women. Oppose state and federal laws that place restrictions on public funding and the use of public facilities in the provision of abortion services.

### **Improve women’s knowledge of medical abortion**

The following recommendations are intended to increase the understanding of medical abortion among women seeking early pregnancy termination. The acceptability of a method depends, in part, upon women having complete and accurate information.

- Promote laws and policies that provide for education and counseling of women seeking abortion services; such education and counseling must include information about all abortion methods.
- Develop and support laws and policies that provide public funding to make

available in public clinics medical abortion-related educational materials.

- Support and promote policies that ensure that education and counseling are culturally appropriate and specific to various age, cultural, and social groups.

## **Ensuring Access to Medical Abortion**

The above recommendations are aimed at making medical abortion easier to provide and more accessible to women.

Implementing these recommendations will help create the conditions necessary for health care providers in the U.S. to offer medical abortion. Although women's knowledge about medical abortion is important, knowledge itself will not improve access to medical abortion. Access will be guaranteed by public policies that support women's health and the right of each woman to decide for herself if and when to have children. The goal of ensuring access to medical abortion will be realized with the cooperation of public health professionals, women's health advocates, health care providers, policy makers, journalists, media professionals, and others who recognize the importance of abortion access to the health of women, men, and their families.



# References

1. Talbot M. The little white bombshell. *New York Times Magazine*. July 11, 1999:38-43, 48, 61-3.
2. Henshaw SK. Abortion incidence and services in the United States, 1995-1996. *Fam Plann Perspect*. 1998;30(6): 263-270, 287.
3. Joffe C, Weitz T. Normalizing the exceptional: Incorporating the "abortion pill" into mainstream medicine. *Soc Sci Med*. In press.
4. Jones R, Henshaw S. Mifepristone for early medical abortion: Experiences in France, Great Britain, and Sweden. *Perspect Sex Reprod Health*. 2002;34(3):154-161.
5. Henshaw SK. Unintended pregnancy in the United States. *Fam Plann Perspect*. 1998;30(1):24-29, 46.
6. Tietze C. The public health effects of legal abortion in the United States. *Fam Plann Perspect*. 1984;16(1):26-28.
7. Pymar HC, Creinin M. Alternatives to mifepristone regimens for medical abortion. *Obstet Gynecol*. 2000;183(2 Supp):S54.
8. Jensen J. Personal communication. June 14, 2002.
9. American College of Obstetrics and Gynecology. *Medical management of abortion*. Washington, DC; April, 2001. ACOG Practice Bulletin #26.
10. Schreiber JR, Bao S. Cervical ripening. *eMedicine Journal* [serial online]. 2001;2(7). Available at: <http://www.emedicine.com/med/topic3282.htm>. Accessed September 17, 2001.
11. Tews L. Personal communication. May 25, 2001.
12. Advances in Health Technology. Mifepristone—Facts at your fingertips. Washington, DC: N.d.
13. Population Council. Mifepristone: A chronology. Available at: <http://www.popcouncil.org/mifeprex/chrono.html>. Accessed April 20, 2001.
14. Reproductive Health Technologies Project. Mifepristone in the U.S.: An unfinished saga. Washington, DC: N.d.
15. Ulmann A. The development of mifepristone: A pharmaceutical drama in three acts. *J Am Med Womens Assoc*. 2000;55(3 Supp):S117-120.
16. Spitz IM, Bardin CW. Clinical pharmacology of RU 486: An anti-progestin and antigluccorticoid. *Contraception*. 1993;48:403-444.
17. US Food and Drug Administration. Mifepristone questions and answers. Available at: <http://fda.gov/cder/drug/infopage/mifepristone/mifepristone-qa.htm>. Accessed January 15, 2001.
18. Creinin MD. Medical abortion regimens: Historical context and overview. *Am J Obstet Gynecol*. 2001;183(2 Supp),S3-9.
19. el-Rafae H, Templeton A. Early induction of abortion by a combination of oral mifepristone and misoprostol administered by the vaginal route. *Contraception*. 1994;49:111-114.
20. Jain JK, Meckstroth KR, Mishell, DR. Early pregnancy termination with intravaginally administered sodium chloride solution-moistened misoprostol tablets: Historical comparison with mifepristone and oral misoprostol. *Am J Obstet Gynecol*. 1999;181:1386-1391.
21. Kahn JG, Becker BJ, MacIsaac L, et al. The effectiveness of medical abortion: A meta-analysis. *Contraception*. 2000;61:29-40.
22. Schaff E, Eisinger SH, Stadalius LS, Franks P, Gore BZ, Poppema S. Low-dose mifepristone 200 mg. and vaginal misoprostol for abortion. *Contraception*. 1999;59:1-6.
23. Schaff EA, Fielding SL, Eisinger SH, Stadalius LS, Fuller L. Low-dose mifepristone followed by vaginal misoprostol at 48 hours for abortion up to 63 days. *Contraception*. 2000;61:41-46.
24. World Health Organization Task Force on Post-ovulatory Methods of Fertility Regulation. Comparison of two doses of mifepristone in combination with misoprostol for early medical abortion: A randomized trial. *BJOG*. 2000;107(4):524-530.

25. Gouk EV, Lincoln K, Khair A, Haslock J, Knight J, Cruickshank DJ. Medical termination of pregnancy at 63 to 83 days gestation. *BJOG*. 1999;106:535-539.
26. Schaff EA, Fielding SL, Westhoff C, et al. Vaginal misoprostol administered 1, 2, or 3 days after mifepristone for early medical abortion: A randomized trial. *JAMA*. 2000;284(15):1948-1953.
27. Schaff EA, Fielding SL, Westhoff C. Randomized trial of oral versus vaginal misoprostol at one day after mifepristone for early medical abortion. *Contraception*. 2001;64(2):81-85.
28. Newhall EP, Winikoff B. Abortion with mifepristone and misoprostol: Regimens, effectiveness, acceptability and future directions. *Obstet Gynecol*. 2000;183(2 Supp):S44-53.
29. Spitz IM, Bardin CW, Benton L, Robbins A. Early pregnancy termination with mifepristone and misoprostol in the United States. *N Engl J Med*. 1998;338(18):1241-1247.
30. National Abortion Federation. Fact sheet: What is medical abortion? Washington, DC:1997.
31. Avrech OM, Golan A, Weinraub Z, Bukovsky I, Caspi E. Mifepristone (RU 486) alone or in combination with a prostaglandin analogue for termination of early pregnancy: A review. *Fertil Steril*. 1991;56(3):385-393.
32. el-Rafaey H, Rajasekar D, Abdalla M, Calder L, Templeton A. Induction of abortion with mifepristone (RU 486) and oral or vaginal misoprostol. *N Engl J Med*. 1995;332(15):983-987.
33. MacNaughton M, Li TC, Killick S, et al. The efficacy and tolerance of mifepristone and prostaglandin in termination of pregnancy of less than 63 days gestation: UK multicentre study—Final results. *Contraception*. 1997;55(1):1-5.
34. Ulmann A, Silvestre L, Chemama L, et al. Medical termination of early pregnancy with mifepristone (RU 486) followed by a prostaglandin analogue: Study in 16,369 women. *Acta Obstet Gynecol Scand*. 1992;71(4):278-283.
35. Winikoff B, Sivin I, Coyaji KJ, et al. Safety, efficacy, and acceptability of medical abortion in China, Cuba, and India: A comparative trial of mifepristone-misoprostol versus surgical abortion. *Am J Obstet Gynecol*. 1997;176(2):431-437.
36. Schaff EA, Fielding SL. A comparison of the Abortion Rights Mobilization and Population Council trials. *JAMWA*. 2000;55(3 Supp):S137-140.
37. Jensen JT, Astley SJ, Morgan E, Nichols MD. Outcomes of suction curettage and mifepristone abortion in the United States. *Contraception*. 1999;59:153-159.
38. Ashok PW, Penney GC, Flett GM, Templeton A. An effective regimen for early medical abortion: A report of 2000 consecutive cases. *Hum Reprod*. 1998;13(10):2962-2965.
39. US Food and Drug Administration. Mifepristone questions and answers. April 17, 2002. Available at: [http://www.fda.gov/cder/drug/infopage/mifepristone/mifepristone-qa\\_4\\_17\\_02htm#4](http://www.fda.gov/cder/drug/infopage/mifepristone/mifepristone-qa_4_17_02htm#4). Accessed September 4, 2002.
40. US Food and Drug Administration. Letter to health care providers. April 19, 2002. Available at: [http://www.fda.gov/medwatch/SAFETY/2002/mifeprex\\_deardoc.PDF](http://www.fda.gov/medwatch/SAFETY/2002/mifeprex_deardoc.PDF). Accessed November 27, 2001.
41. Creinin MD, Aubény E. Medical abortion in early pregnancy. In: Paul M, Lichtenberg ES, Borgatta L, Grimes DA, Stubblefield PG, eds. *A Clinician's Guide to Medical and Surgical Abortion*. New York: Churchill Livingstone; 1999:91-106.
42. Reproductive Health Technologies Project. Overview: Expanding options for early abortion. Washington, DC: N.d.
43. Baird DT. Mode of action of medical methods of abortion. *JAMWA*. 2000;55(3 Supp):S121-126.
44. Creinin MD. Medical abortion with methotrexate 75 mg intramuscularly and vaginal misoprostol. *Contraception*. 1997;56(6):367-371.
45. Creinin MD. Randomized comparison of efficacy, acceptability, and cost of medical versus surgical abortion. *Contraception*. 2000;62(3):117-124.
46. Breitbart V, Rogers MK, VanDerhei D. Medical abortion service delivery. *Am J Obstet Gynecol*. 2000;183(2 Supp):S84-94.
47. Stewart FH, Wells ES, Flinn SK, Weitz TA. *Early Medical Abortion: Issues for Practice*. San Francisco, CA: University of California, San Francisco, Center for Reproductive Health Research and Policy; 2000.
48. Creinin MD. Methotrexate and misoprostol for abortion at 57-63 days gestation. *Contraception*. 1994;50(6):511-515.
49. Creinin MD, Park M. Acceptability of medical abortion with methotrexate and misoprostol. *Contraception*. 1995;52(1):41-44.
50. Creinin MD, Vittinghoff E. Methotrexate and misoprostol versus misoprostol alone for early abortion: A randomized control trial. *JAMA*. 1994;272(15):1190-1195.
51. Creinin MD, Vittinghoff E, Galbraith S, Klaisle C. A randomized trial comparing misoprostol three and seven days after methotrexate for early abortion. *Am J Obstet Gynecol*. 1995;173(5):1578-1584.
52. Creinin MD, Vittinghoff E, Keder L, Darney PD, Tiller G. Methotrexate and misoprostol for early abortion: A multicenter trial. I. Safety and effectiveness. *Contraception*. 1996;53:321-327.

53. Hausknecht RU. Methotrexate and misoprostol to terminate early pregnancy. *N Engl J Med*. 1995;333(9):537-540.
54. Schaff E, Eisinger SH, Franks P, Kim SS. Combined methotrexate and misoprostol for early induced abortion. *Arch Fam Med*. 1995;4(9):774-779.
55. Schaff E, Eisinger, SH, Franks P, Kim SS. Methotrexate and misoprostol for early abortion. *Fam Med*. 1996;28(3):198-203.
56. Wiebe ER. Abortion induced with methotrexate and misoprostol: A comparison of various protocols. *Contraception*. 1997;55:159-163.
57. Creinin MD, Vittinghoff E, Schaff E, Klaisle C, Darney PD, Dean C. Medical abortion with oral methotrexate and vaginal misoprostol. *Obstet and Gynecol*. 1997;90:611-616.
58. Almeling R, Tews L, Dudley S. Abortion training in US obstetrics and gynecology residency programs, 1998. 2000;32(6):268-271, 320.
59. Centers for Disease Control and Prevention. CDC surveillance summaries, December 8, 2000. *MMWR Surveill Summ*. 2000;49(SS-11).
60. Henshaw SK. Barriers to access to abortion services. In: Beckman LJ, Harvey SM, eds. *The New Civil War: The Psychology, Culture, and Politics of Abortion*. Washington, DC: American Psychological Association. 1998:61-80.
61. Cozzarelli C, Major B. The impact of antiabortion activities on women seeking abortions. In: Beckman LJ, Harvey SM, eds. *The New Civil War: The Psychology, Culture, and Politics of Abortion*. Washington, DC: American Psychological Association. 1998:81-104.
62. National Abortion Federation. Violence and disruption statistics: Incidents of violence and disruption against abortion providers. Washington, DC:2000.
63. Henry J. Kaiser Family Foundation. Two national surveys: Views of American and health care providers on medical abortion. Menlo Park, CA:1998.
64. Koenig JD, Tapias MP, Hoff T, Stewart F. Are US health professionals likely to prescribe mifepristone or methotrexate?. *JAMWA*. 2000;55(3):155-160.
65. Ellertson C, Simonds W, Winikoff B, Springer K, Bagchi D. Providing mifepristone- misoprostol medical abortion: the view from the clinic. *JAMWA*. 1999;54(2):91-96.
66. Joffe C. Medical abortion in social context. *Am J Obstet Gynecol*. 2000;183(2 Supp):S10-15.
67. Stewart FH. Improving early options for abortion: It's time to stop waiting. *JAMWA*. 2000;55(3 Supp):S115-117.
68. Henshaw RC, Naji SA, Russell IT, Templeton AA. Comparison of medical abortion with surgical vacuum aspiration: Women's preference and acceptability of treatment. *BMJ*. 1993;307(6906):714-717.
69. Hatcher RA, Trussell, J, Stewart F, et al. *Contraceptive Technology*. 17th rev. ed. New York: Ardent Media Inc.
70. Frye AA, Atrash HK, Lawson HW, McKay T. Induced abortion in the United States: A 1994 update. *JAMWA*. 1994;49(5):131-135.
71. Harvey SM, Beckman LJ, Castle MA, Coeytaux F. Knowledge and perceptions of medical abortion among potential users. *Fam Plann Perspect*. 1995;27(5): 203-207.
72. Harvey SM, Beckman LJ, Branch MR. The relationship of contextual factors to women's perceptions of medical abortion. *Health Care Women Int*. 2002;23(6-7): 654-665.
73. Beckman LJ, Harvey SM. Experience and acceptability of medical abortion with mifepristone and misoprostol among US women. *Womens Health Issues*. 1997;7(4):253- 262.
74. Beckman LJ, Harvey SM. The acceptability of medical abortion to women. In: Beckman LJ, Harvey SM, eds. *The New Civil War: The Psychology, Culture, and Politics of Abortion*. Washington, DC: American Psychological Association; 1998:189-210.
75. Elul B, Pearlman E, Sorhaindo A, Simonds W, Westhoff C. In-depth interviews with medical abortion clients: Thoughts on the method and home administration of misoprostol. *JAMWA*. 2000;55(3 Supp):S169-172.
76. Fielding SL, Edmunds E, Schaff EA. Having an abortion using mifepristone and home misoprostol: A qualitative analysis of women's experiences. *Perspect Sex Reprod Health*. 2002;34(1):34-40.
77. Winikoff B, Ellertson C, Elul B, Sivin I. Acceptability and feasibility of early pregnancy termination by mifepristone-misoprostol. *Arch Fam Med*. 1998;7:360-366.
78. Harvey SM, Beckman LJ, Satre SJ. Choice of and satisfaction with methods of medical abortion among a sample of US clinic patients. *Fam Plan Perspect*. 2001;33(5):212-216.
79. Edwards J, Carson SA. New technologies permit safe abortion at less than six weeks' gestation and provide timely detection of ectopic gestation. *Am J Obstet Gynecol*. 1997;176:1101-1106.
80. Gerhardt A. Personal communication. June 28, 2002.
81. Goldstein SR, Jacot FRM, Poulin C, Poehlmann DS. Documenting pregnancy and gestational age. In: Paul M, Lichtenberg ES, Borgatta L, Grimes DA, Stubblefield PG, eds. *A Clinician's Guide to Medical*

- and Surgical Abortion. Philadelphia, PA: Churchill Livingstone; 1999:39-51.
82. Heilig SL. RU 486: What physicians know, think and (might) do: A survey of California obstetrician/gynecologists. *Law, Medicine & Health Care*. 1992;20(3):184.
  83. Joffe C. Reactions to medical abortion among providers of surgical abortion: An early snapshot. *Fam Plann Perspect*. 1999;31(1): 35-39.
  84. McKee K, Adams E. Nurse midwives' attitudes toward abortion performance and related procedures. *J Nurse Midwifery*. 1994 Sept–Oct;39(5):300-11.
  85. Miller NH, Miller DJ, Pinkston Koenigs LM. Attitudes fo the physician membership of the Society for Adolescent Medicine toward medical abortions for adolescents. *Pediatrics*. 1998;101:E4.
  86. Rosenblatt RA, Mattis R, Hart LG. Abortions in rural Idaho: Physicians' attitudes and practices. *Am J Public Health*. 1995;85(10):1423-1426.
  87. Rosenblatt RA, Robinson KB, Larson EH, Dobie SA. Student education: Medical students' attitudes toward abortion and other health services. *Fam Med*. 1999;31(3):195- 200.
  88. Harvey SM, Beckman LJ, Satre SJ. Experiences and satisfaction with providing methotrexate-induced abortions among US providers. *JAMWA*. 2000;55(3 Supp):S161- 163.
  89. National Right to Life Committee. RU-486 the abortion pill: Risks and dangers. Available at: [http://www.nrlc.org/RU\\_486/ru486factall.PDF](http://www.nrlc.org/RU_486/ru486factall.PDF). Accessed May 21, 2002.
  90. National Abortion Federation. S 251/ HR 482 would impose restrictions on RU-486 (mifepristone) already rejected as medically unnecessary by the FDA. Washington, DC: N.d.
  91. Boonstra H. Voicing concern for women, abortion foes seek limits on availability of mifepristone. *The Guttmacher Report on Public Policy*. 2001;4(2):3-4,7.
  92. National Right to Life Committee. Approval and lingering issues. Available at: <http://www.nrlc.org/ru486/RU486lingeringissues.html>. Accessed May 21, 2002.
  93. Henry J. Kaiser Family Foundation. Danco medical director explains mifepristone's FDA approval not fast-tracked or accelerated, despite media reports. *Kaiser Daily Reproductive Health Report*. March 29, 2001. Available at: [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=3701](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=3701). Accessed May 4, 2002.
  94. US Food and Drug Administration. Summary of labeling changes. April 19, 2002. Available at: <http://www.fda.gov/medwatch/SAFETY/2002/safety02.htm#cytote>. Accessed May 21, 2002.
  95. Zitner A, Savage DG. Abortion pill could be in the hands of voters. *Los Angeles Times*. September 12, 2000:E1.
  96. American College of Obstetrics and Gynecology. Induction of labor with misoprostol. *ACOG Committee Opinion 228*. Washington, DC:1999.
  97. American College of Obstetrics and Gynecology. ACOG news release: ACOG supports use of misoprostol for medical abortion and labor induction. Available at: [http://www.acog.org/from\\_home/publications/press\\_releases/nr11-30-00-3.htm](http://www.acog.org/from_home/publications/press_releases/nr11-30-00-3.htm). Accessed May 3, 2001.
  98. American College of Obstetrics and Gynecology. ACOG news release: ACOG writes FDA on safety of misoprostol. Available at: [http://www.acog.org/from\\_home/publications/press\\_releases/nr10-27-00.htm](http://www.acog.org/from_home/publications/press_releases/nr10-27-00.htm). Accessed April 20, 2001
  99. US Food and Drug Administration. Important drug warning concerning unapproved use of intravaginal or oral misoprostol in pregnant women for induction of labor or abortion. Available at: <http://www.fda.gov/medwatch/safety/2000/cytote.htm>. Accessed November 11, 2001.
  100. Borgmann CE, Jones BS. Legal issues in the provision of medical abortion. *Am J Obstet Gynecol*. 2000;183(2 Supp):S16.
  101. *Armstrong v. State*. 296 Montana 361 (1999).
  102. *Code of Rhode Island Rules*. 2001 ed. 14-000-009.
  103. *Connecticut Attorney General Opinion*. LEXIS 26. July 2, 2001. Available at: <http://www.cslib.org/attys-genl/mainlinks/tabindex7.htm>. Accessed November 30, 2001.
  104. Millock PJ. Letter to Donna Lieberman, New York Civil Liberties Union Foundation. December 20, 1994.
  105. National Abortion Federation. *Early Options: A providers' guide to medical abortion*. [Slide presentation on compact disc]. Washington, DC: National Abortion Federation; 2001.
  106. Jones BS, Heller S. Providing medical abortion: Legal issues of relevance to providers. *JAMWA*. 2000;55(3 Supp):S145-150.
  107. Kolbert K, Jones BS, Miller A, Pangi RL. Legal issues related to abortion in the United States. In: Paul M, Lichtenberg ES, Borgatta L, Grimes DA, Stubblefield PG, eds. *A Clinician's Guide to Medical and Surgical Abortion*. Philadelphia, PA: Churchill Livingstone;1999.
  108. Jones BS. Targeted regulation of abortion providers: Avoiding the "TRAP". Center for Reproductive Law and Policy. Available at: [http://www.crlp.org/pub\\_art\\_trap](http://www.crlp.org/pub_art_trap). Accessed April 28, 2002.

109. Center for Reproductive Law and Policy. Mandatory delays and biased information requirements: Status of mandatory delay and biased information laws. April, 2002. Available at: [http://www.crlp.org/pub\\_fac\\_manddelay1.html](http://www.crlp.org/pub_fac_manddelay1.html). Accessed July 24, 2002.
110. Henry J. Kaiser Family Foundation. Tennessee attorney general says RU-486 is subject to parental notification statutes. *Kaiser Daily Reproductive Health Report*. March 13, 2001. Available at: [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=3362](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=3362). Accessed May 21, 2001.
111. National Abortion Federation. NAF's report on federal and state action on abortion issues. March 2001. Available at: <http://www.prochoice.org/Legal/Legislation/GovRelReps/grp032001.htm>. Accessed May 4, 2001.
112. Henry J. Kaiser Family Foundation. CRLP challenges Michigan law that would ban mention of misoprostol in abortion pamphlets, Los Angeles Times reports. *Kaiser Daily Reproductive Health Report*. February 27, 2001. Available at: [http://www.kaisernetwork.org/Daily\\_reports/print\\_report.cfm?DR\\_ID=3056&dr\\_cat=2](http://www.kaisernetwork.org/Daily_reports/print_report.cfm?DR_ID=3056&dr_cat=2). Accessed May 21, 2001.
113. Henry J. Kaiser Family Foundation. Kentucky Senate passes "conscience" bill allowing pharmacists to refuse dispensation of abortifacients. *Kaiser Daily Reproductive Health Report*. March 5, 2001. Available at: [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=3191](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=3191). Accessed May 21, 2001.
114. Benson J, Clark KA, Gerhardt A, Randall L, Dudley S. *Early abortion services in the United States: Ensuring service availability, remaining on the cutting edge of technology and responding to client demand—Final study report*. Chapel Hill, NC: Ipas; 2001.
115. Ellertson C, Elul B, Winikoff B. Can women use medical abortion without medical supervision?. *Reprod Health Matters*. 1997;9:149-159.
116. Schaff EA, Stadalius LS, Eisinger SH, Franks P. Vaginal misoprostol administered at home after mifepristone (RU 486) for abortion. *J Fam Pract*. 1997;44(4):353-360.
117. Henshaw SK. Personal communication, June 2, 2002.
118. Pymar HC, Creinin MD, Schwartz JL. Mifepristone followed on the same day by vaginal misoprostol for early abortion. *Contraception*. 2001;64(2):87-92.
119. Jensen, J. Personal communication. February 11, 2002.
120. Westfall JM, Sophocles A, Burggraf H, Ellis S. Manual vacuum aspiration for first-trimester abortion. *Arch Fam Med*. 1998;7:559-562.
121. MacIsaac, L, Darney P. Early surgical abortion: An alternative to and backup for medical abortion. *Am J Obstet Gynecol*. 2000;183(2 Supp):S76.
122. Tews, L. Personal communication. June 15, 2001.
123. Gerhardt, A. Personal communication. June 19, 2001.
124. Tews, L. Personal communication. May 16, 2001.

**Abortion provider**– An individual physician or advanced practice clinician who offers abortion services.

**Advanced practice clinicians**– Health care professionals, including nurse practitioners, certified nurse-midwives, and physician assistants, who are licensed to practice medicine with physician supervision.

**Anti-metabolite**– A drug which interferes with cell growth by blocking the chemical reactions necessary for DNA production and normal cell division.

**Anti-progesterone**– A drug which interferes with the action of progesterone, the hormone necessary to cease menstruation and maintain pregnancy.

**Cytotec**®– The brand name for misoprostol (*see Misoprostol*).

**Ectopic pregnancy**– A pregnancy which occurs outside the uterus, also called an *extrauterine pregnancy*. An ectopic pregnancy occurs in about 1 in 60 pregnancies. Often called a “tubal pregnancy,” most ectopic pregnancies occur in the fallopian tubes. However, on rare occasions, the fertilized egg may implant in the ovaries, cervix, or abdomen. Since the fallopian tubes are not large enough to accommodate a growing embryo, the pregnancy cannot continue normally. If the problem is identified early, the embryo is removed. In some cases, the

embryo grows until the fallopian tube is stretched so much that the tube ruptures. Rupture of the tube is a true medical emergency because of maternal hemorrhage (severe blood loss).

**Effectiveness**– In research studies, *effectiveness* usually refers to a drug’s ability to produce the intended result in a real world setting.

**Efficacy**– In research studies, *efficacy* usually refers to a drug’s ability to produce the intended result in a clinical trial.

**Electric vacuum aspiration**– The most common method of surgical abortion in which a small tube, or cannula, is attached to an aspirator machine which is inserted into the uterus; the contents of the uterus are then emptied by suction. Electric vacuum aspiration is a safe and effective abortion method.

**Endometrium**– The mucous membrane that lines the inside of the uterus.

**Evidence-based medicine**– The process of systematically finding, appraising, and using contemporaneous research findings as the basis for clinical decisions.

**FDA**– *see United States Food and Drug Administration*.

**FDA-approved**– Pre-marketing approval of new drugs and certain medical devices required by the FDA. Labels accompanying

the products list only those uses approved by the FDA, and authorized marketing by manufacturers is limited to those uses. However, the FDA does not have the authority to control how doctors use the products once they pass the agency's initial review. Physicians may—and frequently do—prescribe drugs or use devices in ways not included on the FDA-approved label (*see* **Off-label use**).

**Foilex®**— One of the brand names of methotrexate (*see* **Methotrexate**).

**Informed consent**— Except in the case of an emergency, a doctor must obtain a patient's agreement (informed consent) to any course of treatment. Doctors are required to tell the patient anything that would substantially affect the patient's decision. Such information typically includes the nature and purpose of the treatment, its risks and consequences and alternative courses of treatment.

**Last Menstrual Period (LMP)**— The number of days or weeks from the first day of the last menstrual period. This number is used by medical professionals to calculate the gestational age of the embryo or fetus.

**Manual Vacuum Aspiration (MVA)**— A surgical abortion method performed with a handheld syringe as a source of suction for removing uterine contents. MVA may be performed in settings such as doctors' offices, clinics and emergency rooms that lack electric surgical abortion equipment. MVA is as safe and effective as electric vacuum aspiration.

**Medical abortion**— The termination of early pregnancy using a drug or combination of drugs that are usually administered orally, intramuscularly and/or vaginally, first causing the pregnancy to terminate and then causing the uterus to expel the products of conception.

**Methotrexate**— A drug used for medical abortion (usually in combination with misoprostol) which stops cell division in the developing placenta, thereby interfering with cell growth and further attachment to the uterine lining.

**Mifeprex™**— The brand name of mifepristone in the U.S. Mifepristone is also known as RU-486 (*see* **Mifepristone** and **RU- 486**).

**Mifepristone**— A drug used for medical abortion (usually in combination with misoprostol) which alters the uterine lining and disrupts attachment of a fertilized egg. Mifepristone is approved by the FDA for medical abortion.

**Misopristol**— A drug used in combination with mifepristone or methotrexate for medical abortion. Misoprostol softens the cervix and stimulates uterine contractions to expel the products of conception.

**Off-label use**— The practice of prescribing a drug for a disease or a condition other than the indication for which it was approved by the FDA. Off-label use is an integral feature of medical practice and often reflects approaches that have been extensively reported in medical literature. A substantial body of medical and scientific literature has developed around off-label uses, including articles in peer-reviewed professional journals, references in medical textbooks, and discussions and workshops at medical symposia. The American Medical Association estimates that 40-60% of prescriptions are written for off-label uses. The FDA generally bars pharmaceutical and device manufacturers from communicating with physicians and other health care professionals about off-label uses.

**Refusal clauses**— State legislation, also known as "conscience clauses," explicitly allowing some health care professionals or

institutions, often on religious or moral grounds, to refuse to provide or participate in some types of reproductive health care, such as abortion, contraceptive or sterilization services.

**RU-486**– The chemical compound name for mifepristone which was originally developed by the French pharmaceutical company, Rousell-Uclaf (see **Mifepristone** and **Mifeprex**).

**Spontaneous abortion**– The loss of a fetus during pregnancy due to natural causes; a miscarriage is the spontaneous termination of a pregnancy before the fetus has reached 20 weeks.

**Subpart H**– An FDA rule which allows for the regulation of new drugs and expedited review of drugs for serious or life-threatening illnesses. According to the FDA, Mifepristone was approved under Subpart H in order to place safety restrictions on its distribution. The approval of mifepristone was not expedited. The FDA approved mifepristone only after reviewing three complete phases of clinical trials, which is the standard review process. Approval for mifepristone was issued more than four years after the sponsor (Danco Laboratories) submitted its application.

**Surgical back-up**– In the case of medical abortion, refers to arrangements made by a provider for a patient to receive a surgical abortion in the event of an incomplete medical abortion or ongoing pregnancy.

**Ultrasound**–a type of imaging which uses high frequency sound waves; used in determining the gestational age of a pregnancy.

#### **United States Food and Drug**

**Administration (FDA)**– An agency of the Department of Health and Human Services responsible for enforcing laws enacted by

Congress which deal with the regulation of food (excluding meat, poultry and some egg products), drugs, medical devices, blood, biological products (such as vaccines and tissues for transplantation) and cosmetics. The FDA also monitors the safety of the nation's food supply, reviews scientific evidence related to new drugs or medical devices and investigates the safety of commonly used chemicals.



## **The Abortion Access Project**

552 Massachusetts Avenue, Suite 215  
Cambridge, MA 02139  
(617) 661-1161  
[www.abortionaccess.org](http://www.abortionaccess.org)

## **The Alan Guttmacher Institute**

120 Wall Street, 21st Floor  
New York, NY 10005  
(212) 248-1111  
[www.agi-usa.org](http://www.agi-usa.org)

## **American Civil Liberties Union (ACLU)**

Reproductive Freedom Project  
125 Broad Street, 18th Floor  
New York, NY 10004  
[www.aclu.org/issues/reproduct/hmrr.html](http://www.aclu.org/issues/reproduct/hmrr.html)

## **American College of Nurse Midwives**

818 Connecticut Avenue, NW, Suite 900  
Washington, DC 20006  
(202) 728-9860  
[www.midwife.org](http://www.midwife.org)

## **American College of Obstetricians and Gynecologists**

409 12th Street, SW  
P.O. Box 96920  
Washington, DC 20090-6920  
(202) 638-5577  
[www.acog.org](http://www.acog.org)

## **American Medical Women's Association**

801 North Fairfax Street, Suite 400  
Alexandria, VA 22314-1767  
(703) 838-0500  
[www.amwa-doc.org](http://www.amwa-doc.org)

## **American Public Health Association**

800 I Street, NW  
Washington, DC 20001  
(202) 777-2742  
[www.apha.org](http://www.apha.org)

## **Association of Reproductive Health Professionals**

2401 Pennsylvania Avenue, NW, Suite 350  
Washington, DC 20037-1718  
(202) 466-3825  
[www.arhp.org](http://www.arhp.org)

## **Center for Reproductive Health Research & Policy**

UCSF, 3333 California Street  
Suite 335, Box 0744  
San Francisco, CA 94143-0744  
(415) 502-4098  
<http://reprohealth.ucsf.edu>

## **Center for Reproductive Law and Policy**

120 Wall Street, 14th Floor  
New York, NY 10005  
(917) 637-3600  
[www.crlp.org](http://www.crlp.org)

**Clinicians for Choice**

c/o The National Abortion Federation  
1755 Massachusetts Avenue, NW, Suite 600  
Washington, DC 20036  
(202) 667-5881  
[www.cliniciansforchoice.org](http://www.cliniciansforchoice.org)  
Danco Laboratories, LLC (maker of Mifepre™)  
(877) 432-7596  
[www.earlyoptionpill.com](http://www.earlyoptionpill.com)

**Henry J. Kaiser Family Foundation**

2400 Sand Hill Road  
Menlo Park, CA 94025  
(650) 854-9400  
[www.kff.org](http://www.kff.org)

**Ipas**

300 Market Street, Suite 200  
Chapel Hill, NC 27516  
(919) 967-7052, (800) 334-8446  
[www.ipas.org](http://www.ipas.org)

**Medical Students for Choice**

2041 Bancroft Way, Suite 201  
Berkeley, CA 94704  
(510) 540-1195  
[www.ms4c.org](http://www.ms4c.org)

**National Abortion and Reproductive Rights  
Action League**

1156 15th Street, NW, Suite 700  
Washington, DC 20005  
(202) 973-3000  
[www.naral.org](http://www.naral.org)

**National Abortion Federation**

1755 Massachusetts Avenue, NW, Suite 600  
Washington, DC 20036  
(202) 667-5881  
[www.prochoice.org](http://www.prochoice.org)

**National Women's Health Network**

514 10th Street, NW, Suite 400  
Washington, DC 20004  
(202) 347-1140  
[www.womenshealthnetwork.org](http://www.womenshealthnetwork.org)

**National Women's Law Center**

11 Dupont Circle, NW, Suite 800  
Washington, DC 20036  
(202) 588-5180  
[www.nwlc.org](http://www.nwlc.org)

**Physicians for Reproductive Choice  
and Health**

55 West 39th Street, 10th Floor  
New York, NY 10018  
(646) 366-1890  
[www.prch.org](http://www.prch.org)

**Planned Parenthood Federation of America**

810 Seventh Avenue  
New York, NY 10019  
(212) 541-7800, (800) 230-PLAN  
[www.plannedparenthood.org](http://www.plannedparenthood.org)